

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA**

ROBERT M. MILLER,
Plaintiff,

v.

MERRICK B. GARLAND, U.S. Attorney General,
U.S. DEPARTMENT OF JUSTICE; STEVEN
DETTELBAUGH, Director, Bureau of Alcohol
Tobacco, Firearms, and Explosives; BUREAU
OF ALCOHOL, TOBACCO, FIREARMS AND
EXPLOSIVES,
Defendants.

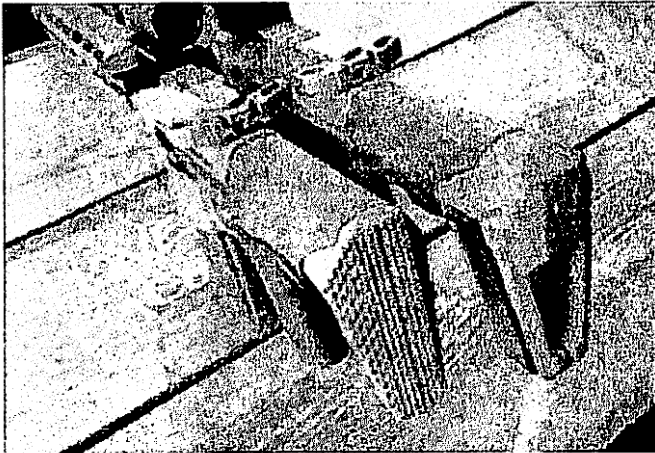
Civ. Case No: 1:23-cv-195

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APPLICATION FOR A NATIONWIDE TEMPORARY RESTRAINING ORDER AND A
PRELIMINARY AND PERMANENT INJUNCTION

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- Exhibit 3: ATF Letter – November 26, 2012
- Exhibit 4: ATF Letter – March 5, 2014
- Exhibit 5: ATF Open Letter – 2015
- Exhibit 6: ATF Letter – December 22, 2015
- Exhibit 7: ATF Letter – March 21, 2017
- Exhibit 8: OMB Circular A-4
- Exhibit 9: Executive Order 12866

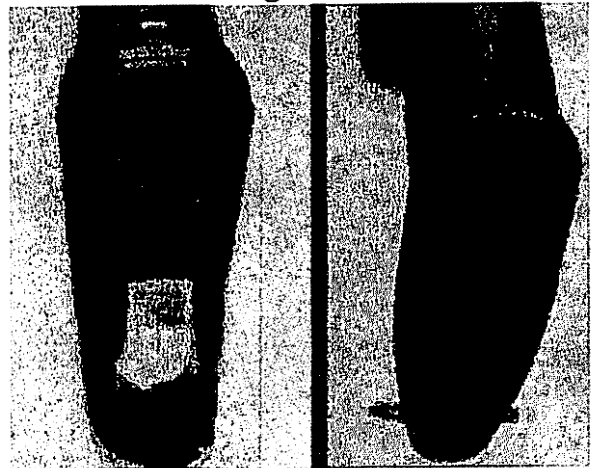
EXHIBIT 1

Figure 1



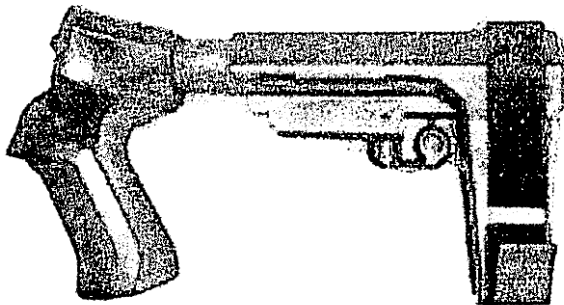
Honey Badger SBR (left) and Pistol (right)

Figure 2



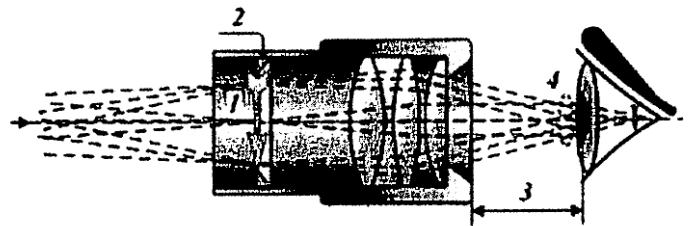
SBA3 Brace (left) and Stock (right)

Figure 3



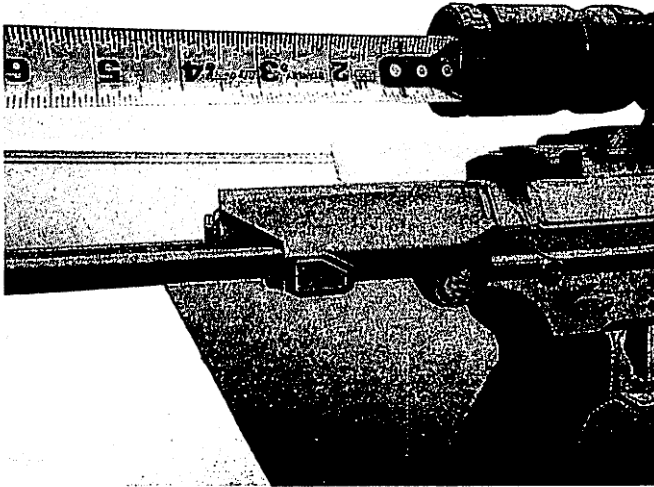
Brace Configured for a Shotgun

Figure 4



Eye Relief

Figure 5



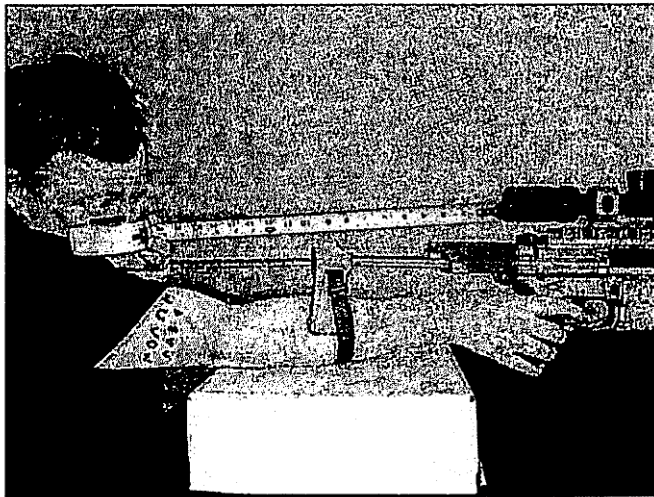
Eye Relief on Plaintiff's QHB 3.8"

Figure 6



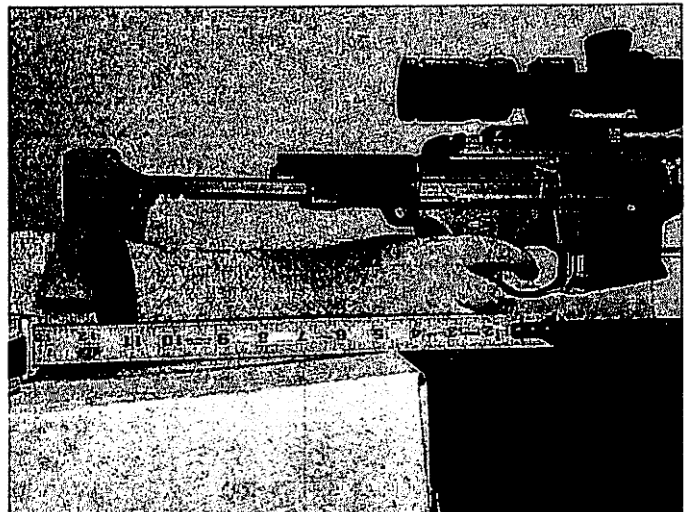
Crystal Clear Reticle w/Eye at 20"

Figure 7



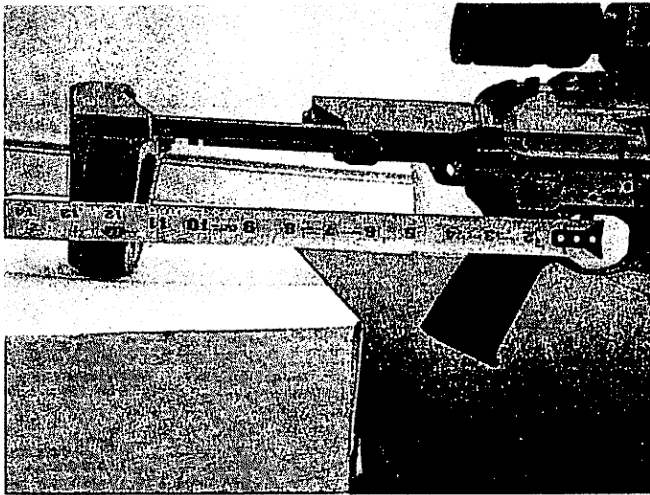
Distance from Ocular Lens to Eye, 20"

Figure 8



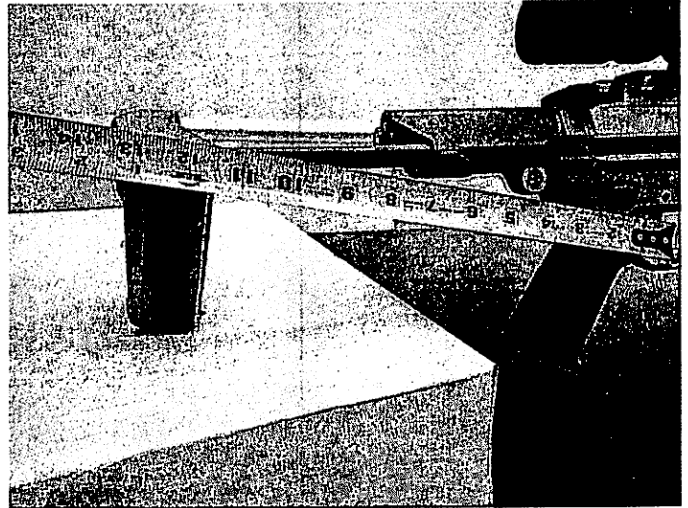
Distance from Trigger to Forearm, 13.2"

Figure 9



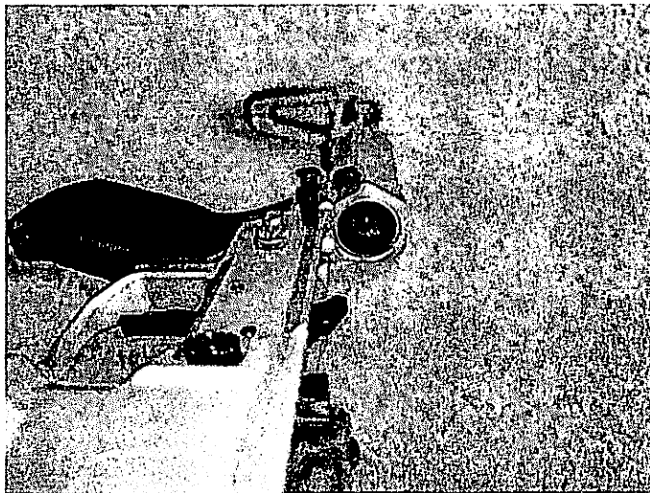
Horizontal Length of Pull, 13.0"

Figure 10



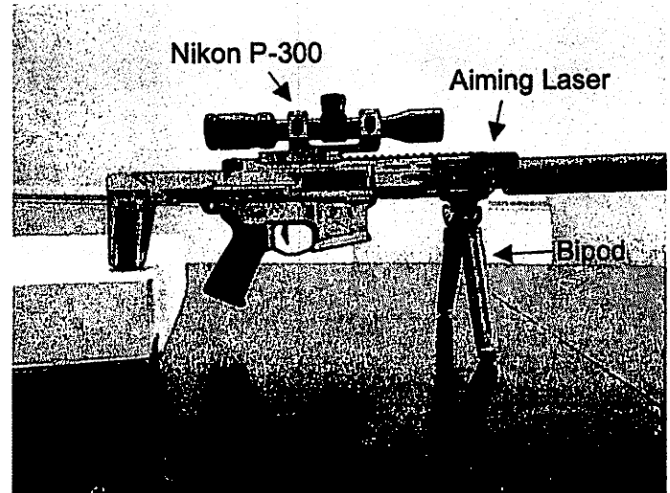
Diagonal Length of Pull, 13.38"

Figure 11



QHB Proprietary Buffer

Figure 12



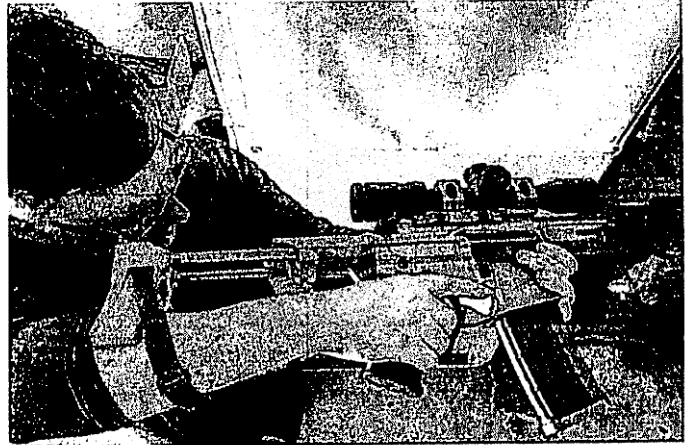
QHB on Bipod w/Scope & Laser

Figure 13



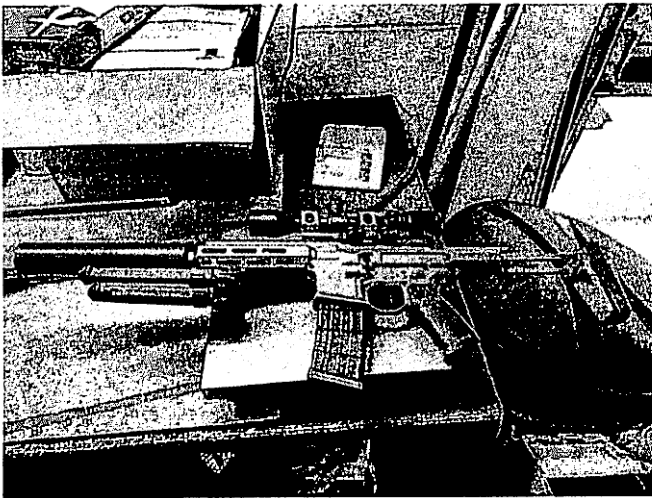
QHB w/Brace, One Hand

Figure 14



QHB w/Brace, Two Hands, Canted 90°

Figure 15



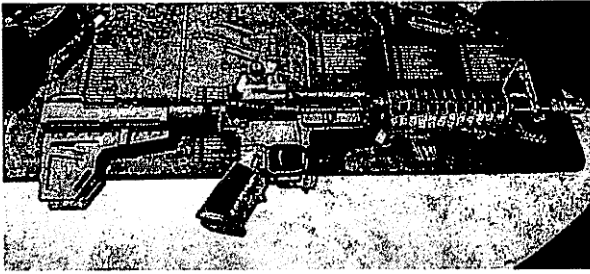
Weighing QHB

Figure 16



QHB at 9.14 Pounds

Figure 17



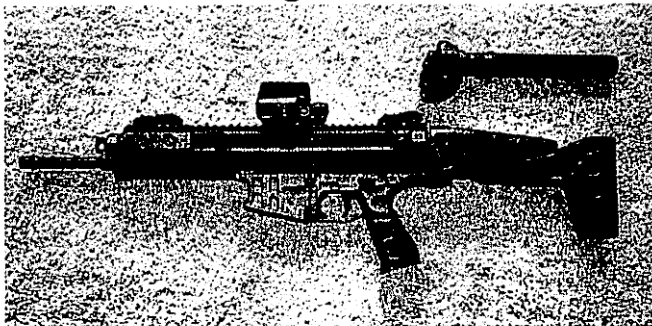
AR Pistol w/Blade

Figure 18



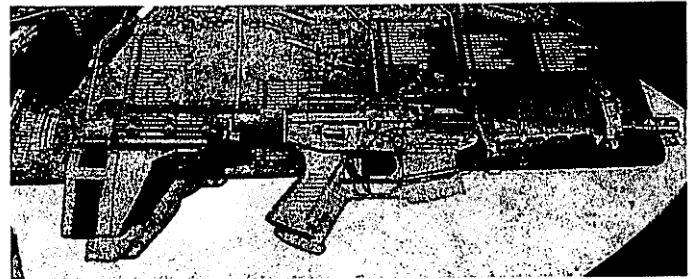
Plaintiff's Braced 300 BLK Pistol

Figure 19



Plaintiff's CZ Bren SBR w/Original Pistol Tube

Figure 20



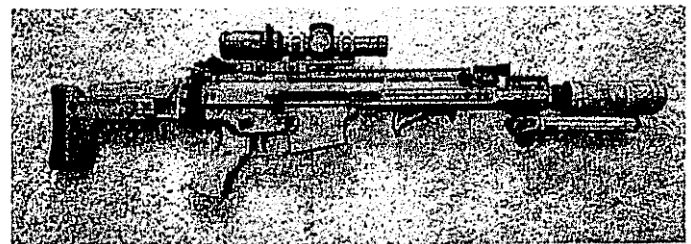
Sig P556 w/Brace

Figure 21



Plaintiff's Galil Ace SBR

Figure 22



Plaintiff's SCAR 17 SBR

Figure 23



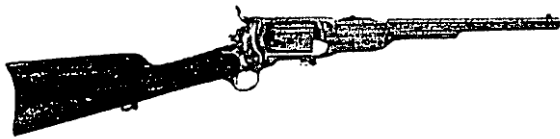
U.S. Army M4 Carbine, 14.5" barrel

Figure 24



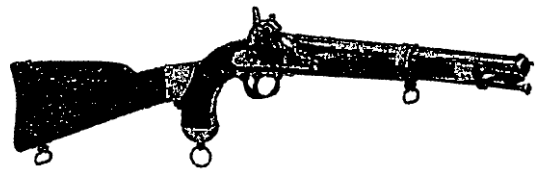
Giovanni Beretta Folding Stock Pistol

Figure 25



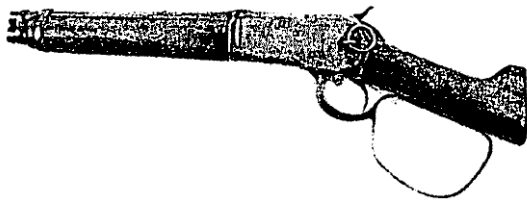
Colt New Model Revolving Rifle, 15" Bbl

Figure 26



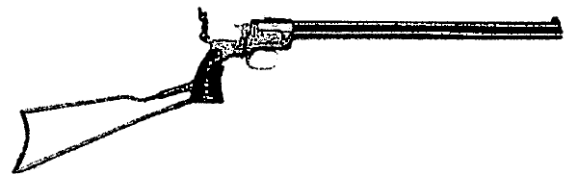
Springfield Model 1855, 12" Barrel

Figure 27



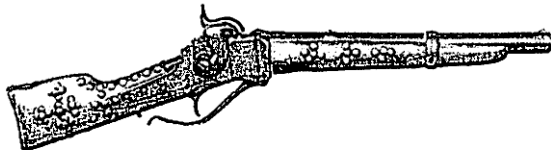
Winchester Model 1892, "Mare's Leg"

Figure 28



Marble's Game Getter, 1908

Figure 29



Sharp's Model 1859 Indian Blanket Gun

Figure 30



British Sea Service Blunderbuss, c. 1750

Figure 31



Wilson Blunderbuss, 11" Barrel, c. 1750

Figure 32



Theophilus Coach Gun, 15.9" Barrel, c. 1800-1815

Figure 33



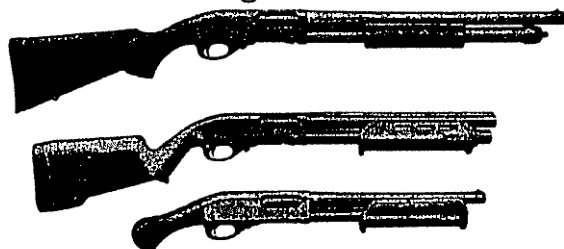
AR Pistol, 10.3" Barrel (top)
AR SBR, 10.3" Barrel (bottom)

Figure 34



Mossberg 590 Shotgun, 18.5" Barrel (top)
Mossberg 590 SBS, 14" Barrel (middle)
Mossberg Shockwave, 14" Barrel (bottom)

Figure 35



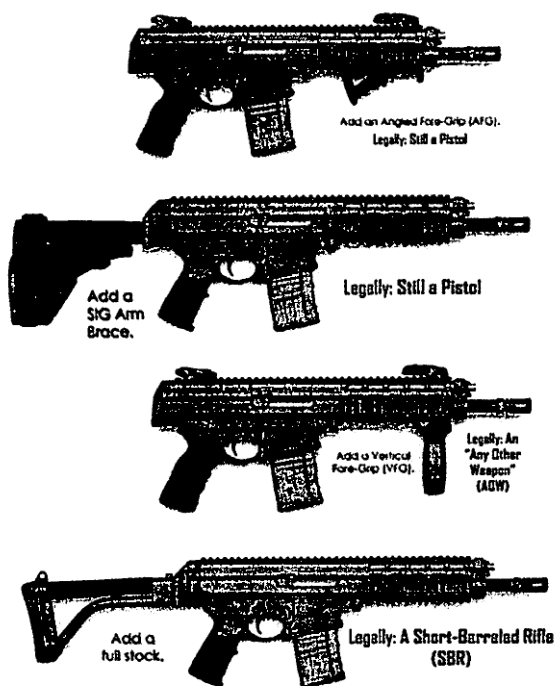
Remington 870, 18.5" Barrel (top)
Remington 870 SBS, 14" Barrel (middle)
Remington TAC-14, 14" Barrel (bottom)

Figure 36



Remington V3 Comp. Shotgun, 22" Bbl (top)
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Figure 37



AR Pistol (top)
AR Pistol with Brace (second)
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AR Short-Barreled Rifle (bottom)

Figure 38



Two-Handed Handgun Shooting
Competitive Shooter (top)
Law Enforcement (middle)
Military (bottom)

Figure 39



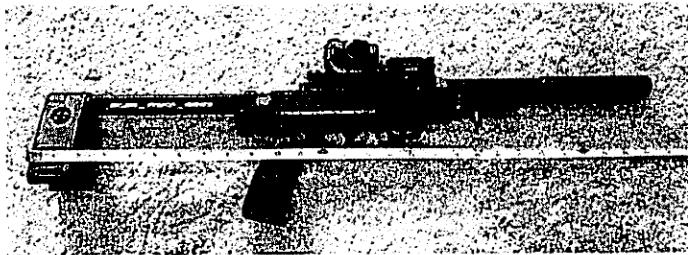
Competitive Shooter Using MP5 SBR

Figure 40



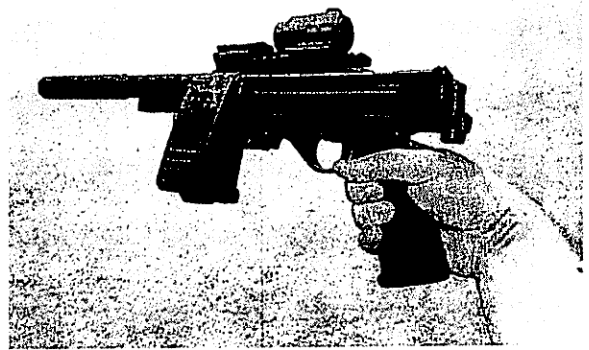
Competitive Shooter Using APC-9 SBR

Figure 41



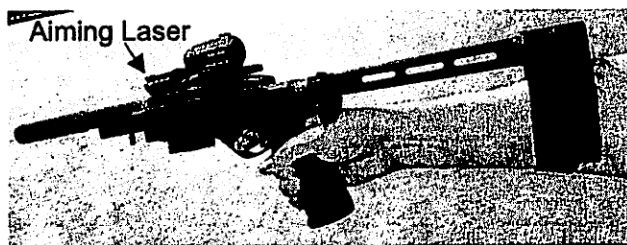
Plaintiff's Ruger 10/22 Pistol w/Brace, 27"

Figure 42



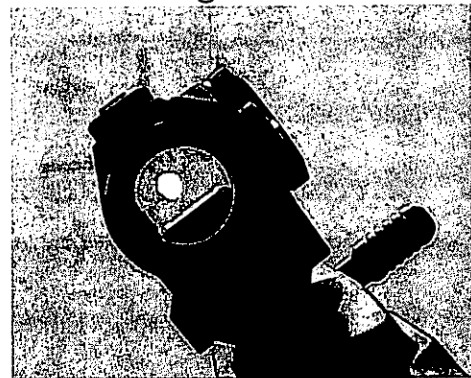
Plaintiff Holding 10/22 Pistol w/Brace Folded

Figure 43



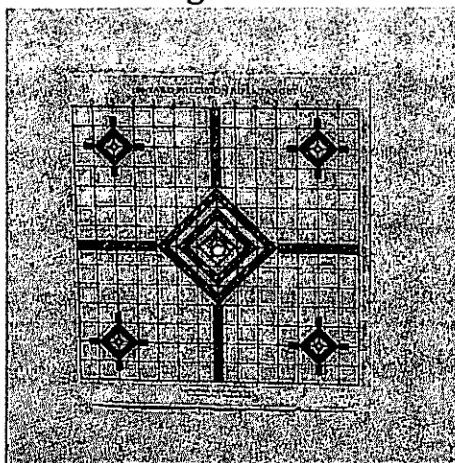
Plaintiff Holding 10/22 Pistol w/Brace

Figure 44



10/22 Red Dot Sight w/Brace, 30° Cant

Figure 45



10/22 Laser Sighting w/Brace, 0° Cant

Figure 46



Ruger 10/22 Charger with Bipod and Scope



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Updated April 19, 2021

Handguns, Stabilizing Braces, and Related Components

On April 7, 2021, the White House announced that the Department of Justice has been directed to issue a proposed rule within 60 days (by June 6, 2021) to clarify when a device marketed as a stabilizing brace might turn a pistol into a short-barreled rifle. On December 18, 2020, the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) published guidance in the *Federal Register* for public comment that indicated that it was preparing to reclassify certain *heavier, larger handguns (pistols) equipped with stabilizing braces* as more stringently regulated *short-barreled rifles*. Such a reclassification would retroactively trigger the more extensive paperwork and background check requirements of the 1934 National Firearms Act (NFA), and require registration of the owner and firearm with ATF. While this guidance was withdrawn on December 23, 2020, the proposed rule could address some of the same issues.

Stabilizing Brace: Shooter's Assist or Shoulder Stock?

Stabilizing braces are devices that can be attached to the rearward portion (breech) of a handgun or other pistol grip firearm's frame or receiver. The brace extends backwards, generally in alignment with the axis of the barrel(s), so the firearm can be secured to the shooter's forearm, while it is held by its pistol grip or other short stock, making a heavier, larger short-stocked firearm easier to handle. The first prototype stabilizing brace was designed to assist a veteran and service-connected amputee with firing an AR-type handgun singlehandedly. Stabilizing braces and similar devices, however, could serve more generally as a quasi-shoulder stock. The addition of shoulder stock to a short-stocked firearm could possibly change a firearm's classification under current law due to definitional differences between the NFA and Gun Control Act of 1968 (GCA).

ATF has long ruled that the attachment of a shoulder stock to a handgun or pistol grip firearm transformed that GCA-regulated firearm into an NFA-regulated short-barreled rifle or shotgun. In November 2012, however, ATF determined that attaching a stabilizing brace to an AR-type pistol would not change that firearm's classification from a solely GCA-regulated handgun to an NFA-regulated short-barreled rifle. Since then, many variations of stabilizing braces have been manufactured and sold in the United States. In 2015, in an Open Letter, ATF raised questions as to the legality of using or intending to use stabilizing braces as shoulder stocks. In several private letters, made public by the addressees, ATF appeared to walk back these considerations. In 2018, however, ATF charged an individual with unlawfully possessing an unregistered short-barreled rifle—an AR-type pistol equipped with a cheek rest, which is arguably a variant of a stabilizing

brace. ATF submitted that this cheek rest, when fully extended, constituted a shoulder stock, because its "length of pull" was greater than 13.5 inches (i.e., the distance from the trigger pad to the end of the cheek rest fully extended). The defendant was found not guilty by a jury, based partly on ATF's failure to take the measurement properly in alignment with the barrel's axis. This case is an example of how the absence of definitive determinations about the legality of firearms equipped with stabilizing braces and similar devices may create repercussions.

GCA- and NFA-Regulated Firearms

When Congress passed the GCA, it significantly amended and repassed the NFA as Title II of that measure. These acts include different, but respective definitions for the term "firearm" (18 U.S.C. §921(a)(3) and 26 U.S.C. §5845(a)). Under these definitions, all firearms regulated under the NFA are first regulated under the GCA. As discussed below, the three basic types of firearms regulated under the GCA are shotguns, rifles, and handguns.

SBSs, SBRs, AOWs, and DDs

The NFA further regulates short-barreled shotguns, or SBSs, and short-barreled rifles, or SBRs: (1) shotguns with barrels less than 18 inches in length, (2) rifles with barrels less than 16 inches in length, or (3) any existing shotgun or rifle that has been modified to be less than 26 inches in overall length by shortening its stock and/or barrel(s). (See 18 U.S.C. §§921(a)(6) and (8), and 26 U.S.C. §5845(a).)

Under "any other weapon," or AOW, the NFA regulates smoothbore handguns (less than 26 inches in overall length) and other "concealable" firearms with combination smoothbore and rifled bore barrels between 12 and 18 inches in length. The AOW classification also captures certain deceptive or disguised firearms (e.g., umbrella, belt buckle, and pen guns). The term "any other weapon" is defined at 26 U.S.C. §5845(e).

Under "destructive device," or DD, the NFA regulates "non-sporting" shotguns; firearms with barrel bore diameters greater than one-half inch (e.g., grenade launchers, bazookas, and mortars); as well as grenades, rockets, mortar rounds, mines, and other explosive devices (e.g., Molotov cocktails). Congress included similar definitions for the term "destructive device" in the GCA and NFA (18 U.S.C. §921(a)(4) and 26 U.S.C. §5845(f)). In addition, the NFA regulates machine guns and firearms silencers, which are beyond the scope of this In Focus.

Shotgun and Rifle Definitions

Congress included identical statutory standalone definitions for the terms "shotgun" and "rifle" under the GCA and NFA. The term "shotgun" means "a weapon designed or

DECLARATION OF [REDACTED]

I, [REDACTED], do hereby declare that I am a resident of the State of California, and that I am the author of the foregoing Declaration of [REDACTED] and the accompanying exhibits, and that I am the owner of the copyright in the foregoing Declaration of [REDACTED] and the accompanying exhibits.

I, [REDACTED], do hereby declare that I am a resident of the State of California, and that I am the author of the foregoing Declaration of [REDACTED] and the accompanying exhibits, and that I am the owner of the copyright in the foregoing Declaration of [REDACTED] and the accompanying exhibits.

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redesigned, made or remade, and intended to be fired from the shoulder and designed or redesigned and made or remade to use the energy of an explosive to fire through a smooth bore either a number of ball shot or a single projectile for each single pull of the trigger” (18 U.S.C. §921(a)(5) and 26 U.S.C. §5845(d)). The term “rifle” means “a weapon designed or redesigned, made or remade, and intended to be fired from the shoulder and designed or redesigned and made or remade to use the energy of an explosive to fire only a single projectile through a rifled bore for each single pull of the trigger” (18 U.S.C. §921(a)(7) and 26 U.S.C. §5845(c)).

From these definitions, it can be deduced that the defining characteristic of a long gun (shotgun or rifle) is that it is intended to be shoulder-fired, from which it follows that the defining feature of a long gun is a *shoulder stock* of some type. In addition, shotguns are “smoothbore.” The barrel of a rifle is “rifled bore,” and consists of lines and grooves machine-cut into the interior of the barrel (the bore) to spin a bullet as it travels at a high velocity down the barrel bore.

Handgun Definition and Other Pistol Grip Firearms
Under the GCA, the term “handgun” means “(A) a firearm which has a short stock and is designed to be held and fired by the use of a single hand; and (B) any combination of parts from which a firearm described in subparagraph (A) can be assembled” (18 U.S.C. §921(a)(29)). From this definition, it can be deduced that the defining feature of a handgun is its *short stock*, and that it is designed to be fired singlehandedly. The term handgun includes both pistols and revolvers (26 C.F.R. §§478.11 and 479.11). Under current law, *rifled bore handguns* are regulated solely under the GCA and there are no restrictions on the barrel or overall length of such handguns.

Smoothbore handguns are regulated under the NFA under the AOW classification. Since at least 1976, however, ATF has adopted 26 inches in overall length as the determining dimension that separates NFA-regulated “concealable” smoothbore handguns, or AOWs, from GCA-regulated short-stocked, smoothbore firearms. ATF adopted this presumptive dimension of concealability from the statutory definitions for short-barreled rifles and shotguns discussed above. ATF refers to these solely GCA-regulated short-stocked, smoothbore firearms, which are greater than 26 inches in overall length, as “pistol grip firearms.” The popularity of pistol grip firearms arguably increased in 2008, when ATF determined that the barrel length was “immaterial” to the classification of such firearms, while the 26 inches in overall length restriction remained unchanged. Prior to this, most firearms makers believed that the barrel of a pistol grip firearm had to be greater than 18 inches.

“Gray Area” in the Law?

In a potentially legal gray area, some GCA-regulated handguns and pistol grip firearms are dimensionally equivalent—in terms of their barrel lengths, overall lengths, and/or barrel bores—to other NFA-regulated firearms. As discussed above, it is unlawful to modify an existing rifle or shotgun by shortening its stock and/or barrel(s) into a short-barreled rifle or shotgun without following the NFA

requirements, which includes remitting a \$200 making tax. However, a handgun with equivalent dimensions does not trigger the NFA requirements, as long as a shoulder stock is never affixed to its frame or receiver.

The same is true for pistol grip firearms. However, ATF holds out the possibility of reclassifying pistol grip firearms as AOWs under the NFA if they are ever used in a concealed manner in the commission of a crime. Others counter that pistol grip firearms would be more properly classified as DDs, under ATF’s reasoning that these short-stocked, smoothbore firearms are “non-handguns” and “non-shotguns,” and are usually firearms with barrel bores of greater than one-half inch in diameter.

Larger, Heavier Handguns, and Pistol Grip Firearms

In the past 16 years, firearms manufacturers in the United States have successfully marketed certain larger, heavier handguns and other pistol grip firearms that arguably push the limits of current law definitions of firearms types and classes under current law. Some of these handguns are assembled around frames and receivers originally designed for AR- and AK-type rifles, and are sometimes chambered for mid-size rifle cartridges and shotgun shells.

Under the 1994-2004 Semiautomatic Assault Weapons (SAW) ban, some of these handguns could have been prohibited under its 50 ounce weight limit (unloaded) and other characteristics that defined an “assault pistol.” The SAW ban did not address pistol grip firearms substantively, as many of these firearms were pump-action, as opposed to semiautomatic, when the ban was enacted. The introduction of stabilizing braces and similar components has significantly increased the popularity of heavier, larger pistols and pistol grip firearms.

In the past eight years, larger, heavier handguns and pistol grip firearms have seen increased sales likely due, in no small part, to stabilizing braces. Most major firearms manufacturers are making firearms equipped with stabilizing braces as part of their featured product lines. While there are no available statistics to gauge authoritatively the number of stabilizing braces already made and sold in the United States, unofficial estimates suggest that there are between 10 and 40 million stabilizing braces and similar components already in civilian hands, either purchased as accessories or already attached to firearms made at home or at the factory. Altering the classification of firearms equipped with stabilizing braces would likely affect millions of owners.

Today, some firearms enthusiasts view GCA-regulated handguns and pistol grip firearms equipped with stabilizing braces as viable alternatives to the more strictly NFA-regulated short-barreled rifles and shotguns. At the same time, gun control advocates have called on ATF to reverse its determinations with regard to stabilizing braces, as well as, larger, heavier handguns and other pistol grip firearms. They view such firearms as “assault pistols” or “assault shotguns,” and have called on Congress to reconstitute an assault weapons ban.



U.S. Department of Justice

Bureau of Alcohol, Tobacco,
Firearms and Explosives

Memorandum for the Director, ATF 903050:MMK
 Date: 03/17/2013 01:12:12 PM 3311/2013-0172

RCV 2 6 2012

This refers to your recent correspondence and accompanying sample sent to the Firearms Technology Branch (FTB), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), for evaluation. You are asking if the addition of this sample, a buffer tube forearm brace, would convert a firearm in a manner that would cause it to be classified as a "rifle" and thus a "firearm" regulated by the National Firearms Act (NFA), specifically, 26 U.S.C. § 5845(a).

The FTB evaluation revealed that the submitted device is constructed of a foam-type rubber (similar to that used in developing prosthetic devices) and two Velcro straps. The device (see enclosed photos) is molded to a pistol style buffer tube for an AR-type firearm, and is shaped to form an upside down "U".

A shooter would insert his or her forearm into the device while gripping the pistol's handgrip—then tighten the Velcro straps for additional support and retention. Thus configured, the device provides the shooter with additional support of a firearm while it is still held and operated with one hand. We find that the device is not designed or intended to fire a weapon from the shoulder.

Based on our evaluation, FTB finds that the submitted forearm brace, when attached to a firearm, does not convert that weapon to be fired from the shoulder and would not alter the classification of a pistol or other firearm. While a firearm so equipped would still be regulated by the Gun Control Act, 18 U.S.C. § 921(a)(3), such a firearm would not be subject to NFA controls.

To facilitate the return of your submitted sample, please arrange for return shipping. This may be done via a UPS "cal-tag" pick-up or simply by using a return shipping label from the U.S. Postal Service or any common carrier. If you wish to accomplish return via "call-tag," please give FTB prior notice so the item can be readied for shipping since UPS will only make three pick-up attempts.



U.S. Department of Justice

**Bureau of Alcohol, Tobacco,
Firearms and Explosives**

Martinsburg, WV 25405

www.atf.gov

**MAR 05 2014 903050:AG
3311/301737**

**Sergeant Joe Bradley
Greenwood Police Department
6060 S Quebec Street
Greenwood Village, Colorado 80111**

Dear Sgt. Bradley:

This is in response to your communication dated January 24, 2014, to the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF). Your e-mail was forwarded to the ATF Firearms Technology Branch (FTB), Martinsburg, West Virginia, for reply. In your note, you ask about firing an AR-15 type pistol from the shoulder; specifically, if doing so would cause the pistol to be reclassified as a Short Barreled Rifle (SBR).

For the following reasons, we have determined that firing a pistol from the shoulder would not cause the pistol to be reclassified as an SBR:

FTB classifies weapons based on their physical design characteristics. While usage/functionality of the weapon does influence the intended design, it is not the sole criterion for determining the classification of a weapon. Generally speaking, we do not classify weapons based on how an individual uses a weapon.

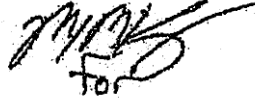
FTB has previously determined (see FTB # 99146) that the firing of a weapon from a particular position, such as placing the receiver extension of an AR-15 type pistol on the user's shoulder, does not change the classification of a weapon. Further, certain firearm accessories such as the SIG Stability Brace have not been classified by FTB as shoulder stocks and, therefore, using the brace improperly does not constitute a design change. Using such an accessory improperly would not change the classification of the weapon per Federal law. However, FTB cannot recommend using a weapon (or weapon accessory) in a manner not intended by the manufacturer.

Sergeant Joe Bradley

Page 2

We thank you for your inquiry and trust the foregoing has been responsive.

Sincerely yours,

A handwritten signature in black ink, appearing to read "EG", with a horizontal line extending from the end of the signature.

For
Earl Griffith
Chief, Firearms Technology Branch

OPEN LETTER ON THE REDESIGN OF “STABILIZING BRACES”

The Firearms and Ammunition Technology Division (FATD), Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) has received inquiries from the public concerning the proper use of devices recently marketed as “stabilizing braces.” These devices are described as “a shooter’s aid that is designed to improve the single-handed shooting performance of buffer tube equipped pistols.” The device claims to enhance accuracy and reduce felt recoil when using an AR-style pistol.

These items are intended to improve accuracy by using the operator’s forearm to provide stable support for the AR-type pistol. ATF has previously determined that attaching the brace to a firearm does not alter the classification of the firearm or subject the firearm to National Firearms Act (NFA) control. However, this classification is based upon the use of the device as designed. When the device is redesigned for use as a shoulder stock on a handgun with a rifled barrel under 16 inches in length, the firearm is properly classified as a firearm under the NFA.

The NFA, 26 USCS § 5845, defines “firearm,” in relevant part, as “a shotgun having a barrel or barrels of less than 18 inches in length” and “a rifle having a barrel or barrels of less than 16 inches in length.” That section defines both “rifle” and “shotgun” as “a weapon designed or *redesigned*, made or remade, and intended to be fired from the shoulder....” (Emphasis added).

Pursuant to the plain language of the statute, ATF and its predecessor agency have long held that a pistol with a barrel less than 16 inches in length and an attached shoulder stock is a NFA “firearm.” For example, in Revenue Ruling 61-45, Luger and Mauser pistols “having a barrel of less than 16 inches in length with an attachable shoulder stock affixed” were each classified as a “short barrel rifle...within the purview of the National Firearms Act.”

In classifying the originally submitted design, ATF considered the objective design of the item as well as the stated purpose of the item. In submitting this device for classification, the designer noted that

The intent of the buffer tube forearm brace is to facilitate one handed firing of the AR15 pistol for those with limited strength or mobility due to a handicap. It also performs the function of sufficiently padding the buffer tube in order to reduce bruising to the forearm while firing with one hand. Sliding and securing the brace onto ones forearm and latching the Velcro straps, distributes the weight of the weapon evenly and assures a snug fit. Therefore, it is no longer necessary to dangerously "muscle" this large pistol during the one handed aiming process, and recoil is dispersed significantly, resulting in more accurate shooting without compromising safety or comfort.

In the classification letter of November 26, 2012, ATF noted that a “shooter would insert his or her forearm into the device while gripping the pistol’s handgrip-then tighten the Velcro straps for additional support and retention. Thus configured, the device provides the shooter with additional support of a firearm while it is still held and operated with one hand.” When strapped to the wrist and used as designed, it is clear the device does not allow the firearm to be fired from the shoulder. Therefore, ATF concluded that, pursuant to the information provided, “the device

-2-

is not designed or intended to fire a weapon from the shoulder.” In making the classification ATF determined that the objective design characteristics of the stabilizing brace supported the stated intent.

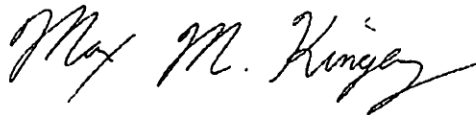
ATF hereby confirms that if used as designed—to assist shooters in stabilizing a handgun while shooting with a single hand—the device is not considered a shoulder stock and therefore may be attached to a handgun without making a NFA firearm. However, ATF has received numerous inquiries regarding alternate uses for this device, including use as a shoulder stock. Because the NFA defines both rifle and shotgun to include any “weapon designed or *redesigned*, made or *remade*, and *intended to be fired from the shoulder*,” any person who *redesigns* a stabilizing brace for use as a shoulder stock makes a NFA firearm when attached to a pistol with a rifled barrel under 16 inches in length or a handgun with a smooth bore under 18 inches in length.

The GCA does not define the term “redesign” and therefore ATF applies the common meaning. “Redesign” is defined as “to alter the appearance or function of.” See e.g. Webster’s II New College Dictionary, Third Ed. (2005). This is not a novel interpretation. For example ATF has previously advised that an individual possesses a destructive device when possessing anti-personnel ammunition with an otherwise unregulated 37/38mm flare launcher. See ATF Ruling 95-3. Further, ATF has advised that even use of an unregulated flare and flare launcher as a weapon results in the making of a NFA weapon. Similarly, ATF has advised that, although otherwise unregulated, the use of certain nail guns as weapons may result in classification as an “any other weapon.”

The pistol stabilizing brace was neither “designed” nor approved to be used as a shoulder stock, and therefore use as a shoulder stock constitutes a “redesign” of the device because a possessor has changed the very function of the item. Any individual letters stating otherwise are contrary to the plain language of the NFA, misapply Federal law, and are hereby revoked.

Any person who intends to use a handgun stabilizing brace as a shoulder stock on a pistol (having a rifled barrel under 16 inches in length or a smooth bore firearm with a barrel under 18 inches in length) must first file an ATF Form 1 and pay the applicable tax because the resulting firearm will be subject to all provisions of the NFA.

If you have any questions about the issues addressed in this letter, you may contact the Firearms and Ammunition Technology Division at fire_tech@atf.gov or by phone at (304) 616-4300.



Max M. Kingery
Acting Chief
Firearms Technology Criminal Branch
Firearms and Ammunition Technology Division



U.S. Department of Justice

Bureau of Alcohol, Tobacco,
Firearms and Explosives

Firearms Technology Industry Services Branch

Martinsburg, WV

www.atf.gov

DEC 22 2015

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3311/304296

Mr. Michael Faucette
Mark Barnes & Associates
1350 I Street NW, Suite 360
Washington, DC 20005

Dear Mr. Faucette:

This refers to your correspondence to the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF), Firearms Technology Industry Services Branch (FTISB), which accompanied your submitted sample of an "Adjustable Pistol Stabilizing Brace" mounted on a semiautomatic pistol. Specifically, you asked whether the subject device could be lawfully installed on a handgun.

As you may be aware, the amended Gun Control Act of 1968 (GCA), 18 U.S.C. § 921(a)(3), defines the term "firearm" to include: *any weapon (including a starter gun) which will or is designed to or may be readily converted to expel a projectile by the action of an explosive...[and] ...the frame or receiver of any such weapon....*

Also, with respect to the definitions of "handgun" and "pistol" under Federal statutes and regulations, you may be aware that the GCA, 18 U.S.C. § 921(a)(29), defines "handgun" to mean, in part *...a firearm which has a short stock and is designed to be held and fired by the use of a single hand....*

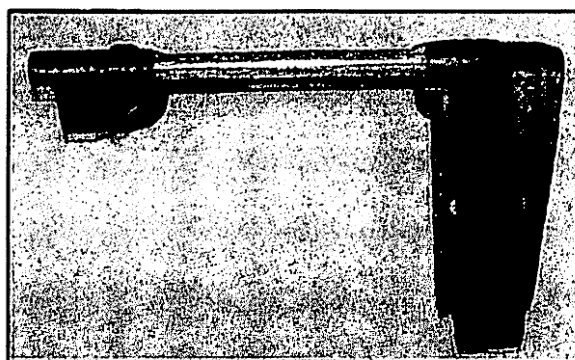
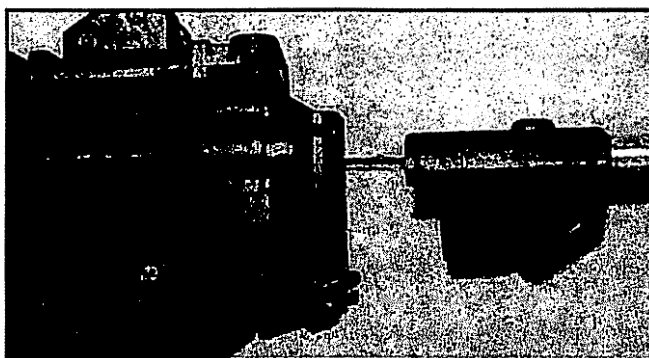
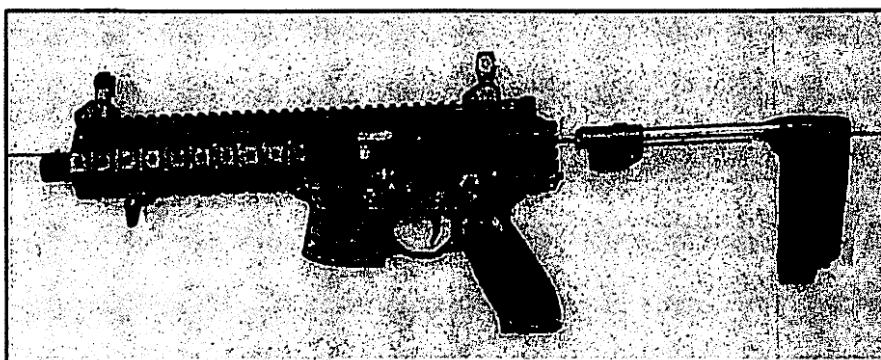
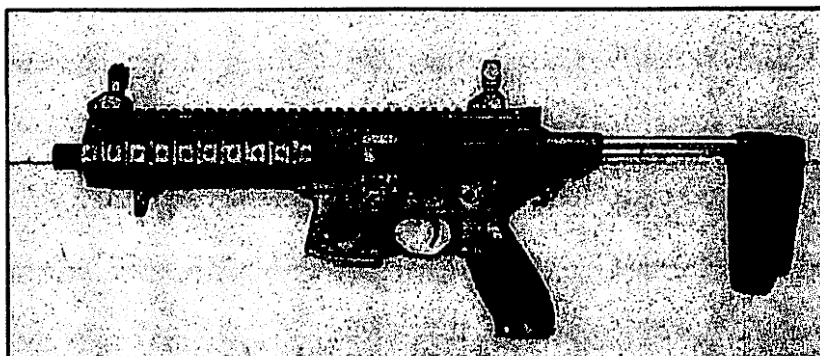
Additionally, 27 CFR § 478.11, a regulation implementing the GCA, defines "pistol" as *...a weapon originally designed, made, and intended to fire a projectile (bullet) from one or more barrels when held in one hand, and having (a) a chamber(s) as an integral part(s) of, or permanently aligned with, the bore(s); and (b) a short stock designed to be gripped by one hand and at an angle to and extending below the line of the bore(s).*

Please note also that the GCA, 18 U.S.C. § 921(a)(7), defines the term "rifle" to include *...a weapon designed or redesigned, made or remade, and intended to be fired from the shoulder....*

Finally, the National Firearms Act (NFA), 26 U.S.C. § 5845(a)(3), defines "firearm" to include *...a rifle having a barrel or barrels of less than 16 inches in length....*

Mr. Michael Faucette

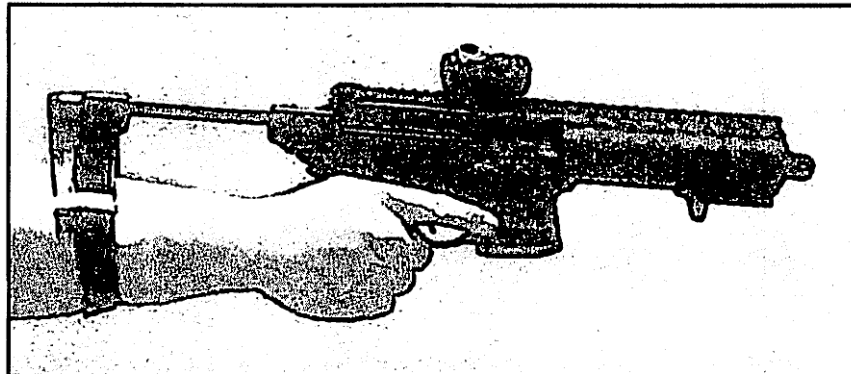
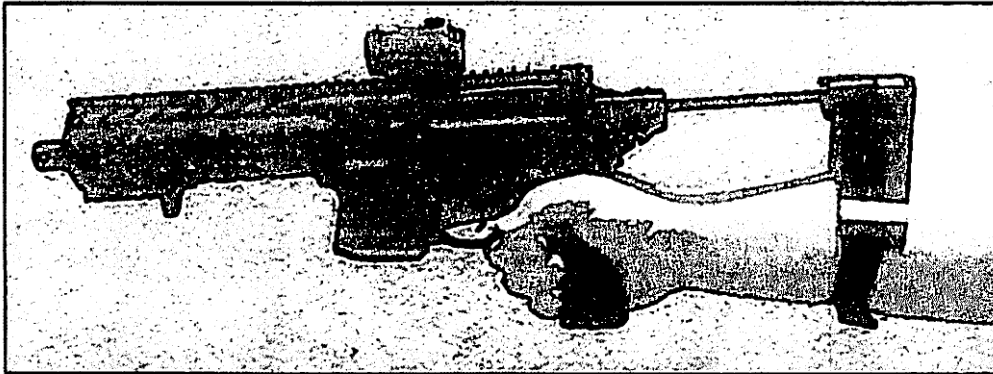
The submitted device (pictured below) utilizes two telescoping metal rods that affix to both sides of an adapter mounted to the rear of a Sig Sauer, Model SIG MPX, 9mm Luger caliber pistol:



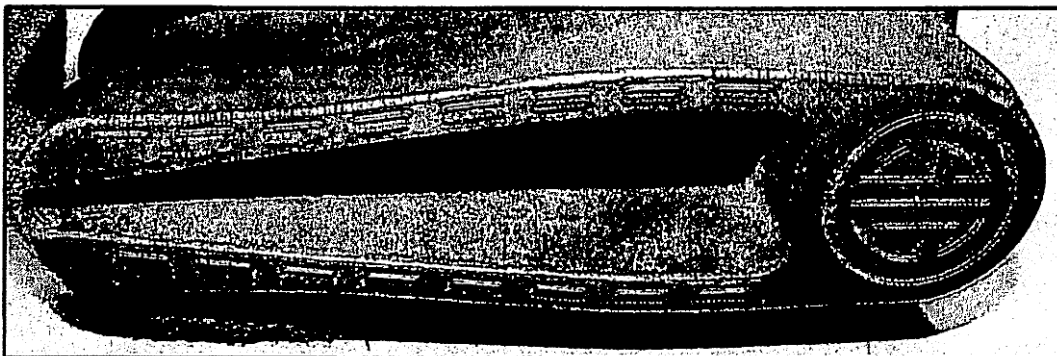
Mr. Michael Faucette

The submitted SIG MPX pistol, with adjustable brace installed, has the following attributes:

- Brace adapter attached to rear of pistol frame.
- Adjustable stabilizing brace attached to adapter.
- Pistol weight without brace attached: 81 ounces.
- Pistol weight with brace attached: 105 ounces.
- Distance from rear of frame to end of fully extended brace: approximately 8-1/4 inches.
- Accessory rails.
- Utilizes a detachable magazine (not submitted).
- 9mm Luger caliber, 8-inch barrel with attached flash suppressor.
- Overall length of approximately 25 inches.



Further, the submitted brace contains a series of raised ridges at its rear (see photo below):



Mr. Michael Faucette

The subject ridges on the rear of the submitted sample serve no functional purpose in the design of a pistol brace; however, the ridges do provide a non-slip, gripping surface, a feature commonly associated with butt stocks/shoulder stocks as well as firearms designed and intended to be fired from the shoulder. You indicate production models will not have this raised surface so as to preclude its usefulness to be shouldered.

The submitted weapon, as described and depicted above, would be classified as a “pistol” subject to GCA provisions; however, it would not be a “firearm” as defined by the NFA provided the “Adjustable Pistol Stabilizing Brace” is used as originally designed; NOT used as a shoulder stock; and the raised ridges are removed from the rear of the brace. Please note that if the subject firearm is concealed on a person, the classification with regard to the NFA may change.

We understand that the current design differs from a previously approved design because of a difference in materials used as well as production cost considerations. We also understand that the device was developed to be shorter than the previous design to allow smaller and/or shorter shooters to effectively utilize a brace.

Central to ATF’s determination is your representation that the purpose and intent of your design, as with previously approved designs, is solely to allow shooters—particularly those with disabilities—to better support large handguns or pistols when firing one-handed. For example, the handgun that you submitted weighs 81 ounces without a magazine installed. Conventional handguns available to the public typically weigh between 20 and 40 ounces, depending on frame material and frame size, without a magazine installed. FTISB believes that the designed use provides support for your position that the submitted sample is not actually intended to be used as a shoulder stock.

Your submission would therefore be approved for use on handguns similar to that attached to your submission, provided there are no raised ridges on the rear of the brace. Its use on smaller, or more conventional handguns, would not be authorized because the purported intent and design offers no benefit for small handguns.

Further, should an individual utilize the “Adjustable Pistol Stabilizing Brace” on the submitted sample as a shoulder stock to fire the weapon from the shoulder, this firearm would then be classified as a “short-barreled rifle” as defined in the NFA, 26 U.S.C. § 5845(a)(3) because the subject firearm, with attached brace, has then been made or remade, designed or redesigned from its originally intended purpose.

In closing, FTISB finds that the submitted sample is approved for use as a pistol stabilizing brace provided the raised ridges are removed from the rear of the device and not added at a later time.

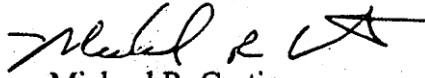
To facilitate return of the submitted item, please provide FTISB with an appropriate FedEx or similar account number within 60 days of receipt of this letter.

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Mr. Michael Faucette

We thank you for your inquiry and trust the foregoing has been responsive.

Sincerely yours,



Michael R. Curtis

Chief, Firearms Technology Industry Services Branch



U.S. Department of Justice

Bureau of Alcohol, Tobacco,
Firearms and Explosives

Assistant Director

Washington, DC 20226
www.atf.gov

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Mark Barnes, Esq.
Outside Counsel to SB Tactical, LLC
1350 Eye St. NW, Suite 260
Washington, D.C. 20005

RECEIVED
AUG 04 2017
BY: FATD

Re: Reversal of ATF Open Letter on the Redesign of "Stabilizing Braces"

Dear Mr. Barnes:

I am writing in response to your letter dated January 5, 2017, to Thomas Brandon, the Acting Director of the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATF) on behalf of your client SB Tactical, LLC. Your letter requests that ATF reconsider its position articulated in ATF's "*Open Letter on the Redesign of 'Stabilizing Braces'*" issued on January 16, 2015 (hereafter, the "*Open Letter*"). The *Open Letter* made it clear that stabilizing braces are perfectly legal accessories for large handguns or pistols. However, when employed as a shoulder stock with a firearm with a barrel less than 16 inches in length, the result would be making an unregistered NFA firearm. Your letter challenges the legal correctness of this latter conclusion and asks that ATF disavow it. Since receiving your letter we have re-examined the conclusions contained in the *Open Letter*. Although we stand by those conclusions, we agree that the *Open Letter* may have generated some confusion concerning the analytical framework by which those conclusions were reached. Thank you for the opportunity to clarify our analysis.

Background

As you are aware, the NFA, 26 USC § 5845, defines "firearm," in relevant part, as "a shotgun having a barrel or barrels of less than 18 inches in length" and "a rifle having a barrel or barrels of less than 16 inches in length." That section defines both "rifle" and "shotgun" as "a weapon designed or redesigned, made or remade, and intended to be fired from the shoulder...." Pursuant to the plain language of the statute, ATF and its predecessor agency have long held that a pistol with a barrel less than 16 inches in length and an attached shoulder stock is an NFA "firearm."

Exhibit 7

DISC-010825

ATF 001575

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Mark Barnes, Esq.

In 2012, ATF determined that a specific arm-stabilizing brace—marketed as “a shooter’s aid” to assist in shooting large buffer tube equipped pistols—was not a shoulder stock and therefore could be attached to a firearm without that act constituting the making of an NFA firearm. Following this determination, the firearms industry and members of the public sought clarification on whether the stabilizing brace may lawfully be used as a shoulder stock. To respond to these inquiries, ATF published the January 2015 *Open Letter*. In that letter ATF confirmed its previous determination that the use of stabilizing braces, as designed, would not create a short-barreled rifle when attached to a firearm. ATF also advised, however, that because the stabilizing brace was not designed as a shoulder stock, “use” of the device as a shoulder stock would constitute a “redesign” of the firearm to which it was attached, resulting in the classification of that firearm as a short-barreled rifle.

Your letter asserts that ATF’s analysis of “use” is untenable because the mere use of an otherwise lawfully possessed item for a purpose for which it was not designed does not constitute “redesign” as defined in the NFA. You support this argument with analogies involving items that are not firearms (*i.e.*, misuse of a screwdriver or hammer), and by distinguishing a prior ATF ruling, ATF Ruling 95-2, on which the *Open Letter* relies in its analysis of use. The unstated, but logical, result of your argument is that stabilizing braces, although designed, intended and marketed for use only to shoot from the arm, could be attached to a firearm and used as a shoulder stock without falling within the purview of the NFA. Under certain circumstances, such an absolute result is simply not consistent with the letter and intent of the NFA, as we illustrate in the next paragraph.

An accessory that can be attached to a firearm in any one of several configurations must be evaluated to determine whether attaching it in each of those configurations constitutes “making” an NFA firearm under both objective and subjective analyses. With respect to stabilizing braces, ATF has concluded that attaching the brace to a handgun as a forearm brace does not “make” a short-barreled rifle because in the configuration as submitted to and approved by FATD, it is not intended to be and cannot comfortably be fired from the shoulder. If, however, the shooter/possessor takes affirmative steps to configure the device for use as a shoulder-stock—for example, configuring the brace so as to permanently affix it to the end of a buffer tube, (thereby creating a length that has no other purpose than to facilitate its use as a stock), removing the arm-strap, or otherwise undermining its ability to be used as a brace – and then in fact shoots the firearm from the shoulder using the accessory as a shoulder stock, that person has objectively “redesigned” the firearm for purposes of the NFA. This conclusion is not based upon the mere fact that the firearm was fired from the shoulder at some point. Therefore, an NFA firearm has not necessarily been made when the device is not re-configured for use as a shoulder stock – even if the attached firearm happens to be fired from the shoulder.

Exhibit 7

DISC-010826

ATF 001576

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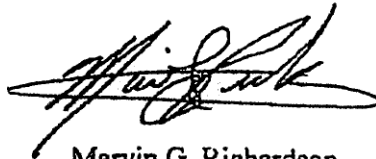
Mark Barnes, Esq.

To the extent the January 2015 *Open Letter* implied or has been construed to hold that incidental, sporadic, or situational "use" of an arm-brace (in its original approved configuration) equipped firearm from a firing position at or near the shoulder was sufficient to constitute "redesign," such interpretations are incorrect and not consistent with ATF's interpretation of the statute or the manner in which it has historically been enforced.

In that regard, we also note that the "making" of an NFA firearm pursuant to 26 U.S.C. § 5821 includes the altering of an existing firearm such that, after the alteration, the firearm meets one of the enumerated descriptions in 26 U.S.C. § 5845(a), whether or not that alteration is permanent. So, for example, one "makes" a short-barreled shotgun subject to the NFA by replacing a 20 inch barrel with a 16 inch barrel, even though that configuration may not be permanent. Nothing in the NFA requires that the "making" be irreversible. Similarly, an item that functions as a stock if attached to a handgun in a manner that serves the objective purpose of allowing the firearm to be fired from the shoulder may result in "making" a short-barreled rifle, even if the attachment is not permanent. *See*, Revenue Ruling 61-45. The fact that the item may allow, or even be intended by its manufacturer for other lawful purposes, does not affect the NFA analysis.

Again, to the extent the *Open Letter* was confusing, we appreciate the opportunity to clarify our position. Thank you for your inquiry regarding this matter.

Sincerely,

A handwritten signature in black ink, appearing to read 'Marvin G. Richardson', with a stylized, flowing script.

Marvin G. Richardson
Assistant Director
Enforcement Programs and Services

Exhibit 7

DISC-010827

ATF 001577

Circular A-4

September 17, 2003

TO THE HEADS OF EXECUTIVE AGENCIES AND ESTABLISHMENTS

Subject: Regulatory Analysis

This Circular provides the Office of Management and Budget's (OMB's) guidance to Federal agencies on the development of regulatory analysis as required under Section 6(a)(3)(c) of Executive Order 12866, "Regulatory Planning and Review," the Regulatory Right-to-Know Act, and a variety of related authorities. The Circular also provides guidance to agencies on the regulatory accounting statements that are required under the Regulatory Right-to-Know Act.

This Circular refines OMB's "best practices" document of 1996 (<http://www.whitehouse.gov/omb/inforeg/riaguide.html>), which was issued as a guidance in 2000 (<http://www.whitehouse.gov/omb/memoranda/m00-08.pdf>), and reaffirmed in 2001 (<http://www.whitehouse.gov/omb/memoranda/m01-23.html>). It replaces both the 1996 "best practices" and the 2000 guidance.

In developing this Circular, OMB first developed a draft that was subject to public comment, interagency review, and peer review. Peer reviewers included Cass Sunstein, University of Chicago; Lester Lave, Carnegie Mellon University; Milton C. Weinstein and James K. Hammitt of the Harvard School of Public Health; Kerry Smith, North Carolina State University; Jonathan Weiner, Duke University Law School; Douglas K. Owens, Stanford University; and W. Kip Viscusi, Harvard Law School. Although these individuals submitted comments, OMB is solely responsible for the final content of this Circular.

A. Introduction

This Circular is designed to assist analysts in the regulatory agencies by defining good regulatory analysis – called either "regulatory analysis" or "analysis" for brevity – and standardizing the way benefits and costs of Federal regulatory actions are measured and reported. Executive Order 12866 requires agencies to conduct a regulatory analysis for economically significant regulatory actions as defined by Section 3(f)(1). This requirement applies to rulemakings that rescind or modify existing rules as well as to rulemakings that establish new requirements.

***The Need for Analysis of Proposed Regulatory Actions*¹**

Regulatory analysis is a tool regulatory agencies use to anticipate and evaluate the likely consequences of rules. It provides a formal way of organizing the evidence on the key effects –

¹ We use the term "proposed" to refer to any regulatory actions under consideration regardless of the stage of the regulatory process.

good and bad – of the various alternatives that should be considered in developing regulations. The motivation is to (1) learn if the benefits of an action are likely to justify the costs or (2) discover which of various possible alternatives would be the most cost-effective.

A good regulatory analysis is designed to inform the public and other parts of the Government (as well as the agency conducting the analysis) of the effects of alternative actions. Regulatory analysis sometimes will show that a proposed action is misguided, but it can also demonstrate that well-conceived actions are reasonable and justified.

Benefit-cost analysis is a primary tool used for regulatory analysis.² Where all benefits and costs can be quantified and expressed in monetary units, benefit-cost analysis provides decision makers with a clear indication of the most efficient alternative, that is, the alternative that generates the largest net benefits to society (ignoring distributional effects). This is useful information for decision makers and the public to receive, even when economic efficiency is not the only or the overriding public policy objective.

It will not always be possible to express in monetary units all of the important benefits and costs. When it is not, the most efficient alternative will not necessarily be the one with the largest quantified and monetized net-benefit estimate. In such cases, you should exercise professional judgment in determining how important the non-quantified benefits or costs may be in the context of the overall analysis. If the non-quantified benefits and costs are likely to be important, you should carry out a “threshold” analysis to evaluate their significance. Threshold or “break-even” analysis answers the question, “How small could the value of the non-quantified benefits be (or how large would the value of the non-quantified costs need to be) before the rule would yield zero net benefits?” In addition to threshold analysis you should indicate, where possible, which non-quantified effects are most important and why.

Key Elements of a Regulatory Analysis

A good regulatory analysis should include the following three basic elements: (1) a statement of the need for the proposed action, (2) an examination of alternative approaches, and (3) an evaluation of the benefits and costs—quantitative and qualitative—of the proposed action and the main alternatives identified by the analysis.

To evaluate properly the benefits and costs of regulations and their alternatives, you will need to do the following:

- Explain how the actions required by the rule are linked to the expected benefits. For example, indicate how additional safety equipment will reduce safety risks. A similar analysis should be done for each of the alternatives.
- Identify a baseline. Benefits and costs are defined in comparison with a clearly stated alternative. This normally will be a “no action” baseline: what the world will be like if the proposed rule is not adopted. Comparisons to a “next best” alternative are also especially useful.

² See Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

- Identify the expected undesirable side-effects and ancillary benefits of the proposed regulatory action and the alternatives. These should be added to the direct benefits and costs as appropriate.

With this information, you should be able to assess quantitatively the benefits and costs of the proposed rule and its alternatives. A complete regulatory analysis includes a discussion of non-quantified as well as quantified benefits and costs. A non-quantified outcome is a benefit or cost that has not been quantified or monetized in the analysis. When there are important non-monetary values at stake, you should also identify them in your analysis so policymakers can compare them with the monetary benefits and costs. When your analysis is complete, you should present a summary of the benefit and cost estimates for each alternative, including the qualitative and non-monetized factors affected by the rule, so that readers can evaluate them.

As you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data. Early consultation can be especially helpful. You should not limit consultation to the final stages of your analytical efforts.

You will find that you cannot conduct a good regulatory analysis according to a formula. Conducting high-quality analysis requires competent professional judgment. Different regulations may call for different emphases in the analysis, depending on the nature and complexity of the regulatory issues and the sensitivity of the benefit and cost estimates to the key assumptions.

A good analysis is transparent. It should be possible for a qualified third party reading the report to see clearly how you arrived at your estimates and conclusions. For transparency's sake, you should state in your report what assumptions were used, such as the time horizon for the analysis and the discount rates applied to future benefits and costs. It is usually necessary to provide a sensitivity analysis to reveal whether, and to what extent, the results of the analysis are sensitive to plausible changes in the main assumptions and numeric inputs.

A good analysis provides specific references to all sources of data, appendices with documentation of models (where necessary), and the results of formal sensitivity and other uncertainty analyses. Your analysis should also have an executive summary, including a standardized accounting statement.

B. The Need for Federal Regulatory Action

Before recommending Federal regulatory action, an agency must demonstrate that the proposed action is necessary. If the regulatory intervention results from a statutory or judicial directive, you should describe the specific authority for your action, the extent of discretion available to you, and the regulatory instruments you might use. Executive Order 12866 states that "Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling need, such as material

failures of private markets to protect or improve the health and safety of the public, the environment, or the well being of the American people"

Executive Order 12866 also states that "Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem." Thus, you should try to explain whether the action is intended to address a significant market failure or to meet some other compelling public need such as improving governmental processes or promoting intangible values such as distributional fairness or privacy. If the regulation is designed to correct a significant market failure, you should describe the failure both qualitatively and (where feasible) quantitatively. You should show that a government intervention is likely to do more good than harm. For other interventions, you should also provide a demonstration of compelling social purpose and the likelihood of effective action. Although intangible rationales do not need to be quantified, the analysis should present and evaluate the strengths and limitations of the relevant arguments for these intangible values.

Market Failure or Other Social Purpose

The major types of market failure include: externality, market power, and inadequate or asymmetric information. Correcting market failures is a reason for regulation, but it is not the only reason. Other possible justifications include improving the functioning of government, removing distributional unfairness, or promoting privacy and personal freedom.

1. Externality, common property resource and public good

An externality occurs when one party's actions impose uncompensated benefits or costs on another party. Environmental problems are a classic case of externality. For example, the smoke from a factory may adversely affect the health of local residents while soiling the property in nearby neighborhoods. If bargaining were costless and all property rights were well defined, people would eliminate externalities through bargaining without the need for government regulation.³ From this perspective, externalities arise from high transactions costs and/or poorly defined property rights that prevent people from reaching efficient outcomes through market transactions.

Resources that may become congested or overused, such as fisheries or the broadcast spectrum, represent common property resources. "Public goods," such as defense or basic scientific research, are goods where provision of the good to some individuals cannot occur without providing the same level of benefits free of charge to other individuals.

2. Market Power

Firms exercise market power when they reduce output below what would be offered in a competitive industry in order to obtain higher prices. They may exercise market power collectively or unilaterally. Government action can be a source of market power, such as when regulatory actions exclude low-cost imports. Generally, regulations that increase market power

³ See Coase RH (1960), *Journal of Law and Economics*, 3, 1-44.

for selected entities should be avoided. However, there are some circumstances in which government may choose to validate a monopoly. If a market can be served at lowest cost only when production is limited to a single producer – local gas and electricity distribution services, for example – a natural monopoly is said to exist. In such cases, the government may choose to approve the monopoly and to regulate its prices and/or production decisions. Nevertheless, you should keep in mind that technological advances often affect economies of scale. This can, in turn, transform what was once considered a natural monopoly into a market where competition can flourish.

3. Inadequate or Asymmetric Information

Market failures may also result from inadequate or asymmetric information. Because information, like other goods, is costly to produce and disseminate, your evaluation will need to do more than demonstrate the possible existence of incomplete or asymmetric information. Even though the market may supply less than the full amount of information, the amount it does supply may be reasonably adequate and therefore not require government regulation. Sellers have an incentive to provide information through advertising that can increase sales by highlighting distinctive characteristics of their products. Buyers may also obtain reasonably adequate information about product characteristics through other channels, such as a seller offering a warranty or a third party providing information.

Even when adequate information is available, people can make mistakes by processing it poorly. Poor information-processing often occurs in cases of low probability, high-consequence events, but it is not limited to such situations. For instance, people sometimes rely on mental rules-of-thumb that produce errors. If they have a clear mental image of an incident which makes it cognitively “available,” they might overstate the probability that it will occur. Individuals sometimes process information in a biased manner, by being too optimistic or pessimistic, without taking sufficient account of the fact that the outcome is exceedingly unlikely to occur. When mistakes in information processing occur, markets may overreact. When it is time-consuming or costly for consumers to evaluate complex information about products or services (e.g., medical therapies), they may expect government to ensure that minimum quality standards are met. However, the mere possibility of poor information processing is not enough to justify regulation. If you think there is a problem of information processing that needs to be addressed, it should be carefully documented.

4. Other Social Purposes

There are justifications for regulations in addition to correcting market failures. A regulation may be appropriate when you have a clearly identified measure that can make government operate more efficiently. In addition, Congress establishes some regulatory programs to redistribute resources to select groups. Such regulations should be examined to ensure that they are both effective and cost-effective. Congress also authorizes some regulations to prohibit discrimination that conflicts with generally accepted norms within our society. Rulemaking may also be appropriate to protect privacy, permit more personal freedom or promote other democratic aspirations.

Showing That Regulation at the Federal Level Is the Best Way to Solve the Problem

Even where a market failure clearly exists, you should consider other means of dealing with the failure before turning to Federal regulation. Alternatives to Federal regulation include antitrust enforcement, consumer-initiated litigation in the product liability system, or administrative compensation systems.

In assessing whether Federal regulation is the best solution, you should also consider the possibility of regulation at the State or local level. In some cases, the nature of the market failure may itself suggest the most appropriate governmental level of regulation. For example, problems that spill across State lines (such as acid rain whose precursors are transported widely in the atmosphere) are probably best addressed by Federal regulation. More localized problems, including those that are common to many areas, may be more efficiently addressed locally.

The advantages of leaving regulatory issues to State and local authorities can be substantial. If public values and preferences differ by region, those differences can be reflected in varying State and local regulatory policies. Moreover, States and localities can serve as a testing ground for experimentation with alternative regulatory policies. One State can learn from another's experience while local jurisdictions may compete with each other to establish the best regulatory policies. You should examine the proper extent of State and local discretion in your rulemaking context.

A diversity of rules may generate gains for the public as governmental units compete with each other to serve the public, but duplicative regulations can also be costly. Where Federal regulation is clearly appropriate to address interstate commerce issues, you should try to examine whether it would be more efficient to retain or reduce State and local regulation. The local benefits of State regulation may not justify the national costs of a fragmented regulatory system. For example, the increased compliance costs for firms to meet different State and local regulations may exceed any advantages associated with the diversity of State and local regulation. Your analysis should consider the possibility of reducing as well as expanding State and local rulemaking.

The role of Federal regulation in facilitating U.S. participation in global markets should also be considered. Harmonization of U.S. and international rules may require a strong Federal regulatory role. Concerns that new U.S. rules could act as non-tariff barriers to imported goods should be evaluated carefully.

The Presumption Against Economic Regulation

Government actions can be unintentionally harmful, and even useful regulations can impede market efficiency. For this reason, there is a presumption against certain types of regulatory action. In light of both economic theory and actual experience, a particularly demanding burden of proof is required to demonstrate the need for any of the following types of regulations:

- price controls in competitive markets;

- production or sales quotas in competitive markets;
- mandatory uniform quality standards for goods or services if the potential problem can be adequately dealt with through voluntary standards or by disclosing information of the hazard to buyers or users; or
- controls on entry into employment or production, except (a) where indispensable to protect health and safety (e.g., FAA tests for commercial pilots) or (b) to manage the use of common property resources (e.g., fisheries, airwaves, Federal lands, and offshore areas).

C. Alternative Regulatory Approaches

Once you have determined that Federal regulatory action is appropriate, you will need to consider alternative regulatory approaches. Ordinarily, you will be able to eliminate some alternatives through a preliminary analysis, leaving a manageable number of alternatives to be evaluated according to the formal principles of the Executive Order. The number and choice of alternatives selected for detailed analysis is a matter of judgment. There must be some balance between thoroughness and the practical limits on your analytical capacity. With this qualification in mind, you should nevertheless explore modifications of some or all of a regulation's attributes or provisions to identify appropriate alternatives. The following is a list of alternative regulatory actions that you should consider.

Different Choices Defined by Statute

When a statute establishes a specific regulatory requirement and the agency is considering a more stringent standard, you should examine the benefits and costs of reasonable alternatives that reflect the range of the agency's statutory discretion, including the specific statutory requirement.

Different Compliance Dates

The timing of a regulation may also have an important effect on its net benefits. Benefits may vary significantly with different compliance dates where a delay in implementation may result in a substantial loss in future benefits (e.g., a delay in implementation could result in a significant reduction in spawning stock and jeopardize a fishery). Similarly, the cost of a regulation may vary substantially with different compliance dates for an industry that requires a year or more to plan its production runs. In this instance, a regulation that provides sufficient lead time is likely to achieve its goals at a much lower overall cost than a regulation that is effective immediately.

Different Enforcement Methods

Compliance alternatives for Federal, State, or local enforcement include on-site inspections, periodic reporting, and noncompliance penalties structured to provide the most appropriate incentives. When alternative monitoring and reporting methods vary in their benefits and costs, you should identify the most appropriate enforcement framework. For example, in

some circumstances random monitoring or parametric monitoring will be less expensive and nearly as effective as continuous monitoring.

Different Degrees of Stringency

In general, both the benefits and costs associated with a regulation will increase with the level of stringency (although marginal costs generally increase with stringency, whereas marginal benefits may decrease). You should study alternative levels of stringency to understand more fully the relationship between stringency and the size and distribution of benefits and costs among different groups.

Different Requirements for Different Sized Firms

You should consider setting different requirements for large and small firms, basing the requirements on estimated differences in the expected costs of compliance or in the expected benefits. The balance of benefits and costs can shift depending on the size of the firms being regulated. Small firms may find it more costly to comply with regulation, especially if there are large fixed costs required for regulatory compliance. On the other hand, it is not efficient to place a heavier burden on one segment of a regulated industry solely because it can better afford the higher cost. This has the potential to load costs on the most productive firms, costs that are disproportionate to the damages they create. You should also remember that a rule with a significant impact on a substantial number of small entities will trigger the requirements set forth in the Regulatory Flexibility Act. (5 U.S.C. 603(c), 604).

Different Requirements for Different Geographic Regions

Rarely do all regions of the country benefit uniformly from government regulation. It is also unlikely that costs will be uniformly distributed across the country. Where there are significant regional variations in benefits and/or costs, you should consider the possibility of setting different requirements for the different regions.

Performance Standards Rather than Design Standards

Performance standards express requirements in terms of outcomes rather than specifying the means to those ends. They are generally superior to engineering or design standards because performance standards give the regulated parties the flexibility to achieve regulatory objectives in the most cost-effective way. In general, you should take into account both the cost savings to the regulated parties of the greater flexibility and the costs of assuring compliance through monitoring or some other means.

Market-Oriented Approaches Rather than Direct Controls

Market-oriented approaches that use economic incentives should be explored. These alternatives include fees, penalties, subsidies, marketable permits or offsets, changes in liability or property rights (including policies that alter the incentives of insurers and insured parties), and required bonds, insurance or warranties. One example of a market-oriented approach is a

program that allows for averaging, banking, and/or trading (ABT) of credits for achieving additional emission reductions beyond the required air emission standards. ABT programs can be extremely valuable in reducing costs or achieving earlier or greater benefits, particularly when the costs of achieving compliance vary across production lines, facilities, or firms. ABT can be allowed on a plant-wide, firm-wide, or region-wide basis rather than vent by vent, provided this does not produce unacceptable local air quality outcomes (such as "hot spots" from local pollution concentration).

Informational Measures Rather than Regulation

If intervention is contemplated to address a market failure that arises from inadequate or asymmetric information, informational remedies will often be preferred. Measures to improve the availability of information include government establishment of a standardized testing and rating system (the use of which could be mandatory or voluntary), mandatory disclosure requirements (e.g., by advertising, labeling, or enclosures), and government provision of information (e.g., by government publications, telephone hotlines, or public interest broadcast announcements). A regulatory measure to improve the availability of information, particularly about the concealed characteristics of products, provides consumers a greater choice than a mandatory product standard or ban.

Specific informational measures should be evaluated in terms of their benefits and costs. Some effects of informational measures are easily overlooked. The costs of a mandatory disclosure requirement for a consumer product will include not only the cost of gathering and communicating the required information, but also the loss of net benefits of any information displaced by the mandated information. The other costs also may include the effect of providing information that is ignored or misinterpreted, and inefficiencies arising from the incentive that mandatory disclosure may give to overinvest in a particular characteristic of a product or service.

Where information on the benefits and costs of alternative informational measures is insufficient to provide a clear choice between them, you should consider the least intrusive informational alternative sufficient to accomplish the regulatory objective. To correct an informational market failure it may be sufficient for government to establish a standardized testing and rating system without mandating its use, because competing firms that score well according to the system should thereby have an incentive to publicize the fact.

D. Analytical Approaches

Both benefit-cost analysis (BCA) and cost-effectiveness analysis (CEA) provide a systematic framework for identifying and evaluating the likely outcomes of alternative regulatory choices. A major rulemaking should be supported by both types of analysis wherever possible. Specifically, you should prepare a CEA for all major rulemakings for which the primary benefits are improved public health and safety to the extent that a valid effectiveness measure can be developed to represent expected health and safety outcomes. You should also perform a BCA for major health and safety rulemakings to the extent that valid monetary values can be assigned to the primary expected health and safety outcomes. In undertaking these analyses, it is important to keep in mind the larger objective of analytical consistency in

estimating benefits and costs across regulations and agencies, subject to statutory limitations. Failure to maintain such consistency may prevent achievement of the most risk reduction for a given level of resource expenditure. For all other major rulemakings, you should carry out a BCA. If some of the primary benefit categories cannot be expressed in monetary units, you should also conduct a CEA. In unusual cases where no quantified information on benefits, costs and effectiveness can be produced, the regulatory analysis should present a qualitative discussion of the issues and evidence.

Benefit-Cost Analysis

A distinctive feature of BCA is that both benefits and costs are expressed in monetary units, which allows you to evaluate different regulatory options with a variety of attributes using a common measure.⁴ By measuring incremental benefits and costs of successively more stringent regulatory alternatives, you can identify the alternative that maximizes net benefits.

The size of net benefits, the absolute difference between the projected benefits and costs, indicates whether one policy is more efficient than another. The ratio of benefits to costs is not a meaningful indicator of net benefits and should not be used for that purpose. It is well known that considering such ratios alone can yield misleading results.

Even when a benefit or cost cannot be expressed in monetary units, you should still try to measure it in terms of its physical units. If it is not possible to measure the physical units, you should still describe the benefit or cost qualitatively. For more information on describing qualitative information, see the section “*Developing Benefit and Cost Estimates*.”

When important benefits and costs cannot be expressed in monetary units, BCA is less useful, and it can even be misleading, because the calculation of net benefits in such cases does not provide a full evaluation of all relevant benefits and costs.

You should exercise professional judgment in identifying the importance of non-quantified factors and assess as best you can how they might change the ranking of alternatives based on estimated net benefits. If the non-quantified benefits and costs are likely to be important, you should recommend which of the non-quantified factors are of sufficient importance to justify consideration in the regulatory decision. This discussion should also include a clear explanation that support designating these non-quantified factors as important. In this case, you should also consider conducting a threshold analysis to help decision makers and other users of the analysis to understand the potential significance of these factors to the overall analysis.

Cost-Effectiveness Analysis⁵

⁴ Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

⁵ For a full discussion of CEA, see Gold, ML, Siegel, JE, Russell, LB, and Weinstein, MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York.

Cost-effectiveness analysis can provide a rigorous way to identify options that achieve the most effective use of the resources available without requiring monetization of all of relevant benefits or costs. Generally, cost-effectiveness analysis is designed to compare a set of regulatory actions with the same primary outcome (e.g., an increase in the acres of wetlands protected) or multiple outcomes that can be integrated into a single numerical index (e.g., units of health improvement).

Cost-effectiveness results based on averages need to be treated with great care. They suffer from the same drawbacks as benefit-cost ratios. The alternative that exhibits the smallest cost-effectiveness ratio may not be the best option, just as the alternative with the highest benefit-cost ratio is not always the one that maximizes net benefits. Incremental cost-effectiveness analysis (discussed below) can help to avoid mistakes that can occur when policy choices are based on average cost-effectiveness.

CEA can also be misleading when the "effectiveness" measure does not appropriately weight the consequences of the alternatives. For example, when effectiveness is measured in tons of reduced pollutant emissions, cost-effectiveness estimates will be misleading unless the reduced emissions of diverse pollutants result in the same health and environmental benefits.

When you have identified a range of alternatives (e.g., different levels of stringency), you should determine the cost-effectiveness of each option compared with the baseline as well as its incremental cost-effectiveness compared with successively more stringent requirements. Ideally, your CEA would present an array of cost-effectiveness estimates that would allow comparison across different alternatives. However, analyzing all possible combinations is not practical when there are many options (including possible interaction effects). In these cases, you should use your judgment to choose reasonable alternatives for careful consideration.

When constructing and comparing incremental cost-effectiveness ratios, you should be careful to determine whether the various alternatives are mutually exclusive or whether they can be combined. If they can be combined, you should consider which might be favored under different regulatory budget constraints (implicit or explicit). You should also make sure that inferior alternatives identified by the principles of strong and weak dominance are eliminated from consideration.⁶

The value of CEA is enhanced when there is consistency in the analysis across a diverse set of possible regulatory actions. To achieve consistency, you need to carefully construct the two key components of any CEA: the cost and the "effectiveness" or performance measures for the alternative policy options.

With regard to measuring costs, you should be sure to include all the relevant costs to society – whether public or private. Rulemakings may also yield cost savings (e.g., energy savings associated with new technologies). The numerator in the cost-effectiveness ratio should reflect net costs, defined as the gross cost incurred to comply with the requirements (sometimes

⁶ Gold ML, Siegel JE, Russell LB, and Weinstein MC (1996), *Cost Effectiveness in Health and Medicine: The Report of the Panel on Cost-Effectiveness in Health and Medicine*, Oxford University Press, New York, pp. 284-285.

called "total" costs) minus any cost savings. You should be careful to avoid double-counting effects in both the numerator and the denominator of the cost-effectiveness ratios. For example, it would be incorrect to reduce gross costs by an estimated monetary value on life extension if life-years are already used as the effectiveness measure in the denominator.

In constructing measures of "effectiveness", final outcomes, such as lives saved or life-years saved, are preferred to measures of intermediate outputs, such as tons of pollution reduced, crashes avoided, or cases of disease avoided. Where the quality of the measured unit varies (e.g., acres of wetlands vary substantially in terms of their ecological benefits), it is important that the measure capture the variability in the value of the selected "outcome" measure. You should provide an explanation of your choice of effectiveness measure.

Where regulation may yield several different beneficial outcomes, a cost-effectiveness comparison becomes more difficult to interpret because there is more than one measure of effectiveness to incorporate in the analysis. To arrive at a single measure you will need to weight the value of disparate benefit categories, but this computation raises some of the same difficulties you will encounter in BCA. If you can assign a reasonable monetary value to all of the regulation's different benefits, then you should do so. But in this case, you will be doing BCA, not CEA.

When you can estimate the monetary value of *some* but not all of the ancillary benefits of a regulation, but cannot assign a monetary value to the primary measure of effectiveness, you should subtract the monetary estimate of the ancillary benefits from the gross cost estimate to yield an estimated net cost. (This net cost estimate for the rule may turn out to be negative – that is, the monetized benefits exceed the cost of the rule.) If you are unable to estimate the value of some of the ancillary benefits, the cost-effectiveness ratio will be overstated, and this should be acknowledged in your analysis. CEA does not yield an unambiguous choice when there are benefits or costs that have not been incorporated in the net-cost estimates. You also may use CEA to compare regulatory alternatives in cases where the statute specifies the level of benefits to be achieved.

The Effectiveness Metric for Public Health and Safety Rulemakings

When CEA is applied to public health and safety rulemakings, one or more measures of effectiveness must be selected that permits comparison of regulatory alternatives. Agencies currently use a variety of effectiveness measures.

There are relatively simple measures such as the number of lives saved, cases of cancer reduced, and cases of paraplegia prevented. Sometimes these measures account only for mortality information, such as the number of lives saved and the number of years of life saved. There are also more comprehensive, integrated measures of effectiveness such as the number of "equivalent lives" (ELs) saved and the number of "quality-adjusted life years" (QALYs) saved.

The main advantage of the integrated measures of effectiveness is that they account for a rule's impact on morbidity (nonfatal illness, injury, impairment and quality of life) as well as premature death. The inclusion of morbidity effects is important because (a) some illnesses (e.g.,

asthma) cause more instances of pain and suffering than they do premature death, (b) some population groups are known to experience elevated rates of morbidity (e.g., the elderly and the poor) and thus have a strong interest in morbidity measurement⁷, and (c) some regulatory alternatives may be more effective at preventing morbidity than premature death (e.g., some advanced airbag designs may diminish the nonfatal injuries caused by airbag inflation without changing the frequency of fatal injury prevented by airbags).

However, the main drawback of these integrated measures is that they must meet some restrictive assumptions to represent a valid measure of individual preferences.⁸ For example, a QALY measure implicitly assumes that the fraction of remaining lifespan an individual would give up for an improvement in health-related quality of life does not depend on the remaining lifespan. Thus, if an individual is willing to give up 10 years of life among 50 remaining years for a given health improvement, he or she would also be willing to give up 1 year of life among 5 remaining years. To the extent that individual preferences deviate from these assumptions, analytic results from CEA using QALYs could differ from analytic results based on willingness-to-pay-measures.⁹ Though willingness to pay is generally the preferred economic method for evaluating preferences, the CEA method, as applied in medicine and health, does not evaluate health changes using individual willingness to pay. When performing CEA, you should consider using at least one integrated measure of effectiveness when a rule creates a significant impact on both mortality and morbidity.

When CEA is performed in specific rulemaking contexts, you should be prepared to make appropriate adjustments to ensure fair treatment of all segments of the population. Fairness is important in the choice and execution of effectiveness measures. For example, if QALYs are used to evaluate a lifesaving rule aimed at a population that happens to experience a high rate of disability (i.e., where the rule is not designed to affect the disability), the number of life years saved should not necessarily be diminished simply because the rule saves the lives of people with life-shortening disabilities. Both analytic simplicity and fairness suggest that the estimated number of life years saved for the disabled population should be based on average life expectancy information for the relevant age cohorts. More generally, when numeric adjustments are made for life expectancy or quality of life, analysts should prefer use of population averages rather than information derived from subgroups dominated by a particular demographic or income group.

OMB does not require agencies to use any specific measure of effectiveness. In fact, OMB encourages agencies to report results with multiple measures of effectiveness that offer different insights and perspectives. The regulatory analysis should explain which measures were selected and why, and how they were implemented.

The analytic discretion provided in choice of effectiveness measure will create some inconsistency in how agencies evaluate the same injuries and diseases, and it will be difficult for

⁷ Russell LB and Sisk JE (2000), "Modeling Age Differences in Cost Effectiveness Analysis", *International Journal of Technology Assessment in Health Care*, 16(4), 1158-1167.

⁸ Pliskin JS, Shepard DS, and Weinstein MC (1980), "Utility Functions for Life Years and Health Status," *Operations Research*, 28(1), 206-224.

⁹ Hammitt JK (2002), "QALYs Versus WTP," *Risk Analysis*, 22(5), pp. 985-1002.

OMB and the public to draw meaningful comparisons between rulemakings that employ different effectiveness measures. As a result, agencies should use their web site to provide OMB and the public with the underlying data, including mortality and morbidity data, the age distribution of the affected populations, and the severity and duration of disease conditions and trauma, so that OMB and the public can construct apples-to-apples comparisons between rulemakings that employ different measures.

There are sensitive technical and ethical issues associated with choosing one or more of these integrated measures for use throughout the Federal government. The Institute of Medicine (IOM) may assemble a panel of specialists in cost-effectiveness analysis and bioethics to evaluate the advantages and disadvantages of these different measures and other measures that have been suggested in the academic literature. OMB believes that the IOM guidance will provide Federal agencies and OMB useful insight into how to improve the measurement of effectiveness of public health and safety regulations.

Distributional Effects

Those who bear the costs of a regulation and those who enjoy its benefits often are not the same people. The term "distributional effect" refers to the impact of a regulatory action across the population and economy, divided up in various ways (e.g., income groups, race, sex, industrial sector, geography). Benefits and costs of a regulation may also be distributed unevenly over time, perhaps spanning several generations. Distributional effects may arise through "transfer payments" that stem from a regulatory action as well. For example, the revenue collected through a fee, surcharge in excess of the cost of services provided, or tax is a transfer payment.

Your regulatory analysis should provide a separate description of distributional effects (i.e., how both benefits and costs are distributed among sub-populations of particular concern) so that decision makers can properly consider them along with the effects on economic efficiency. Executive Order 12866 authorizes this approach. Where distributive effects are thought to be important, the effects of various regulatory alternatives should be described quantitatively to the extent possible, including the magnitude, likelihood, and severity of impacts on particular groups. You should be alert for situations in which regulatory alternatives result in significant changes in treatment or outcomes for different groups. Effects on the distribution of income that are transmitted through changes in market prices can be important, albeit sometimes difficult to assess. Your analysis should also present information on the streams of benefits and costs over time in order to provide a basis for assessing intertemporal distributional consequences, particularly where intergenerational effects are concerned.

E. Identifying and Measuring Benefits and Costs

This Section provides guidelines for your preparation of the benefit and cost estimates required by Executive Order 12866 and the "Regulatory Right-to-Know Act." The discussions in previous sections will help you identify a workable number of alternatives for consideration in your analysis and an appropriate analytical approach to use.

General Issues

1. Scope of Analysis

Your analysis should focus on benefits and costs that accrue to citizens and residents of the United States. Where you choose to evaluate a regulation that is likely to have effects beyond the borders of the United States, these effects should be reported separately. The time frame for your analysis should cover a period long enough to encompass all the important benefits and costs likely to result from the rule.

2. Developing a Baseline

You need to measure the benefits and costs of a rule against a baseline. This baseline should be the best assessment of the way the world would look absent the proposed action. The choice of an appropriate baseline may require consideration of a wide range of potential factors, including:

- evolution of the market,
- changes in external factors affecting expected benefits and costs,
- changes in regulations promulgated by the agency or other government entities, and
- the degree of compliance by regulated entities with other regulations.

It may be reasonable to forecast that the world absent the regulation will resemble the present. If this is the case, however, your baseline should reflect the future effect of current government programs and policies. For review of an existing regulation, a baseline assuming “no change” in the regulatory program generally provides an appropriate basis for evaluating regulatory alternatives. When more than one baseline is reasonable and the choice of baseline will significantly affect estimated benefits and costs, you should consider measuring benefits and costs against alternative baselines. In doing so you can analyze the effects on benefits and costs of making different assumptions about other agencies’ regulations, or the degree of compliance with your own existing rules. In all cases, you must evaluate benefits and costs against the same baseline. You should also discuss the reasonableness of the baselines used in the sensitivity analyses. For each baseline you use, you should identify the key uncertainties in your forecast.

EPA’s 1998 final PCB disposal rule provides a good example of using different baselines. EPA used several alternative baselines, each reflecting a different interpretation of existing regulatory requirements. In particular, one baseline reflected a literal interpretation of EPA’s 1979 rule and another the actual implementation of that rule in the year immediately preceding the 1998 revision. The use of multiple baselines illustrated the substantial effect changes in EPA’s implementation policy could have on the cost of a regulatory program. In the years after EPA adopted the 1979 PCB disposal rule, changes in EPA policy -- especially allowing the disposal of automobile “shredder fluff” in municipal landfills -- reduced the cost of the program by more than \$500 million per year.

In some cases, substantial portions of a rule may simply restate statutory requirements that would be self-implementing, even in the absence of the regulatory action. In these cases,

you should use a pre-statute baseline. If you are able to separate out those areas where the agency has discretion, you may also use a post-statute baseline to evaluate the discretionary elements of the action.

3. Evaluation of Alternatives

You should describe the alternatives available to you and the reasons for choosing one alternative over another. As noted previously, alternatives that rely on incentives and offer increased flexibility are often more cost-effective than more prescriptive approaches. For instance, user fees and information dissemination may be good alternatives to direct command-and-control regulation. Within a command-and-control regulatory program, performance-based standards generally offer advantages over standards specifying design, behavior, or manner of compliance.

You should carefully consider all appropriate alternatives for the key attributes or provisions of the rule. The previous discussion outlines examples of appropriate alternatives. Where there is a "continuum" of alternatives for a standard (such as the level of stringency), you generally should analyze at least three options: the preferred option; a more stringent option that achieves additional benefits (and presumably costs more) beyond those realized by the preferred option; and a less stringent option that costs less (and presumably generates fewer benefits) than the preferred option.

You should choose reasonable alternatives deserving careful consideration. In some cases, a regulatory program will focus on an option that is near or at the limit of technical feasibility. In this case, the analysis would not need to examine a more stringent option. For each of the options analyzed, you should compare the anticipated benefits to the corresponding costs.

It is not adequate simply to report a comparison of the agency's preferred option to the chosen baseline. Whenever you report the benefits and costs of alternative options, you should present both total and incremental benefits and costs. You should present incremental benefits and costs as differences from the corresponding estimates associated with the next less-stringent alternative.¹⁰ It is important to emphasize that incremental effects are simply differences between successively more stringent alternatives. Results involving a comparison to a "next best" alternative may be especially useful.

In some cases, you may decide to analyze a wide array of options. In 1998, DOE analyzed a large number of options in setting new energy efficiency standards for refrigerators and freezers and produced a rich amount of information on their relative effects. This analysis -- examining more than 20 alternative performance standards for one class of refrigerators with top-mounted freezers -- enabled DOE to select an option that produced \$200 more in estimated net benefits per refrigerator than the least attractive option.

¹⁰ For the least stringent alternative, you should estimate the incremental benefits and costs relative to the baseline. Thus, for this alternative, the incremental effects would be the same as the corresponding totals. For each alternative that is more stringent than the least stringent alternative, you should estimate the incremental benefits and costs relative to the closest less-stringent alternative.

You should analyze the benefits and costs of different regulatory provisions separately when a rule includes a number of distinct provisions. If the existence of one provision affects the benefits or costs arising from another provision, the analysis becomes more complicated, but the need to examine provisions separately remains. In this case, you should evaluate each specific provision by determining the net benefits of the proposed regulation with and without it.

Analyzing all possible combinations of provisions is impractical if the number is large and interaction effects are widespread. You need to use judgment to select the most significant or relevant provisions for such analysis. You are expected to document all of the alternatives that were considered in a list or table and which were selected for emphasis in the main analysis.

You should also discuss the statutory requirements that affect the selection of regulatory approaches. If legal constraints prevent the selection of a regulatory action that best satisfies the philosophy and principles of Executive Order 12866, you should identify these constraints and estimate their opportunity cost. Such information may be useful to Congress under the Regulatory Right-to-Know Act.

4. Transparency and Reproducibility of Results

Because of its influential nature and its special role in the rulemaking process, it is appropriate to set minimum quality standards for regulatory analysis. You should provide documentation that the analysis is based on the best reasonably obtainable scientific, technical, and economic information available. To achieve this, you should rely on peer-reviewed literature, where available, and provide the source for all original information.

A good analysis should be transparent and your results must be reproducible. You should clearly set out the basic assumptions, methods, and data underlying the analysis and discuss the uncertainties associated with the estimates. A qualified third party reading the analysis should be able to understand the basic elements of your analysis and the way in which you developed your estimates.

To provide greater access to your analysis, you should generally post it, with all the supporting documents, on the internet so the public can review the findings. You should also disclose the use of outside consultants, their qualifications, and history of contracts and employment with the agency (e.g., in a preface to the RIA). Where other compelling interests (such as privacy, intellectual property, trade secrets, etc.) prevent the public release of data or key elements of the analysis, you should apply especially rigorous robustness checks to analytic results and document the analytical checks used.

Finally, you should assure compliance with the Information Quality Guidelines for your agency and OMB's "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies" ("data quality guidelines") <http://www.whitehouse.gov/omb/fedreg/reproducible.html>.

Developing Benefit and Cost Estimates

1. Some General Considerations

The analysis document should discuss the expected benefits and costs of the selected regulatory option and any reasonable alternatives. How is the proposed action expected to provide the anticipated benefits and costs? What are the monetized values of the potential real incremental benefits and costs to society? To present your results, you should:

- include separate schedules of the monetized benefits and costs that show the type and timing of benefits and costs, and express the estimates in this table in constant, undiscounted dollars (for more on discounting see “*Discount Rates*” below);
- list the benefits and costs you can quantify, but cannot monetize, including their timing;
- describe benefits and costs you cannot quantify; and
- identify or cross-reference the data or studies on which you base the benefit and cost estimates.

When benefit and cost estimates are uncertain (for more on this see “*Treatment of Uncertainty*” below), you should report benefit and cost estimates (including benefits of risk reductions) that reflect the full probability distribution of potential consequences. Where possible, present probability distributions of benefits and costs and include the upper and lower bound estimates as complements to central tendency and other estimates.

If fundamental scientific disagreement or lack of knowledge prevents construction of a scientifically defensible probability distribution, you should describe benefits or costs under plausible scenarios and characterize the evidence and assumptions underlying each alternative scenario.

2. The Key Concepts Needed to Estimate Benefits and Costs

“Opportunity cost” is the appropriate concept for valuing both benefits and costs. The principle of “willingness-to-pay” (WTP) captures the notion of opportunity cost by measuring what individuals are willing to forgo to enjoy a particular benefit. In general, economists tend to view WTP as the most appropriate measure of opportunity cost, but an individual’s “willingness-to-accept” (WTA) compensation for not receiving the improvement can also provide a valid measure of opportunity cost.

WTP and WTA are comparable measures under special circumstances. WTP and WTA measures may be comparable in the following situations: if a regulation affects a price change rather than a quantity change; the change being evaluated is small; there are reasonably close substitutes available; and the income effect is small.¹¹ However, empirical evidence from experimental economics and psychology shows that even when income/wealth effects are “small”, the measured differences between WTP and WTA can be large.¹² WTP is generally

¹¹ See Hanemann WM (1991), *American Economic Review*, 81(3), 635-647.

¹² See Kahneman D, Knetsch JL, and Thaler RH (1991), “Anomalies: The Endowment Effect, Loss Aversion, and Status Quo Bias,” *Journal of Economic Perspectives* 3(1), 192-206.

considered to be more readily measurable. Adoption of WTP as the measure of value implies that individual preferences of the affected population should be a guiding factor in the regulatory analysis.

Market prices provide rich data for estimating benefits and costs based on willingness-to-pay if the goods and services affected by the regulation are traded in well-functioning competitive markets. The opportunity cost of an alternative includes the value of the benefits forgone as a result of choosing that alternative. The opportunity cost of banning a product -- a drug, food additive, or hazardous chemical -- is the forgone net benefit (i.e., lost consumer and producer surplus¹³) of that product, taking into account the mitigating effects of potential substitutes.

The use of any resource has an opportunity cost regardless of whether the resource is already owned or has to be purchased. That opportunity cost is equal to the net benefit the resource would have provided in the absence of the requirement. For example, if regulation of an industrial plant affects the use of additional land or buildings within the existing plant boundary, the cost analysis should include the opportunity cost of using the additional land or facilities.

To the extent possible, you should monetize any such forgone benefits and add them to the other costs of that alternative. You should also try to monetize any cost savings as a result of an alternative and either add it to the benefits or subtract it from the costs of that alternative. However, you should not assume that the "avoided" costs of not doing another regulatory alternative represent the benefits of a regulatory action where there is no direct, necessary relationship between the two. You should also be careful when the costs avoided are attributable to an existing regulation. Even when there is a direct relationship between the two regulatory actions, the use of avoided costs is problematic because the existing regulation may not maximize net benefits and thus may itself be questionable policy. (See the section, "Direct Use of Market Data," for more detail.)

Estimating benefits and costs when market prices are hard to measure or markets do not exist is more difficult. In these cases, you need to develop appropriate proxies that simulate market exchange. Estimates of willingness-to-pay based on revealed preference methods can be quite useful. As one example, analysts sometimes use "hedonic price equations" based on multiple regression analysis of market behavior to simulate market prices for the commodity of interest. The hedonic technique allows analysts to develop an estimate of the price for specific attributes associated with a product. For instance, a house is a product characterized by a variety of attributes including the number of rooms, total floor area, and type of heating and cooling. If there are enough data on transactions in the housing market, it is possible to develop an estimate of the implicit price for specific attributes, such as the implicit price of an additional bathroom or for central air conditioning. This technique can be extended, as well, to develop an estimate for

¹³ Consumer surplus is the difference between what a consumer pays for a unit of a good and the maximum amount the consumer would be willing to pay for that unit. It is measured by the area between the price and the demand curve for that unit. Producer surplus is the difference between the amount a producer is paid for a unit of a good and the minimum amount the producer would accept to supply that unit. It is measured by the area between the price and the supply curve for that unit.

the implicit price of public goods that are not directly traded in markets. An analyst can develop implicit price estimates for public goods like air quality and access to public parks by assessing the effects of these goods on the housing market. Going through the analytical process of deriving benefit estimates by simulating markets may also suggest alternative regulatory strategies that create such markets.

You need to guard against double-counting, since some attributes are embedded in other broader measures. To illustrate, when a regulation improves the quality of the environment in a community, the value of real estate in the community generally rises to reflect the greater attractiveness of living in a better environment. Simply adding the increase in property values to the estimated value of improved public health would be double counting if the increase in property values reflects the improvement in public health. To avoid this problem you should separate the embedded effects on the value of property arising from improved public health. At the same time, an analysis that fails to incorporate the consequence of land use changes when accounting for costs will not capture the full effects of regulation.

3. Revealed Preference Methods

Revealed preference methods develop estimates of the value of goods and services -- or attributes of those goods and services -- based on actual market decisions by consumers, workers and other market participants. If the market participant is well informed and confronted with a real choice, it may be feasible to determine accurately and precisely the monetary value needed for a rulemaking. There is a large and well-developed literature on revealed preference in the peer-reviewed, applied economics literature.

Although these methods are well grounded in economic theory, they are sometimes difficult to implement given the complexity of market transactions and the paucity of relevant data. When designing or evaluating a revealed preference study, the following principles should be considered:

- the market should be competitive. If the market isn't competitive (e.g., monopoly, oligopoly), then you should consider making adjustments such that the price reflects the true value to society (often called the "shadow price");
- the market should not exhibit a significant information gap or asymmetric information problem. If the market suffers from information problems, then you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the market should not exhibit an externality. In this case, you should discuss the divergence of the price from the underlying shadow price and consider possible adjustments to reflect the underlying shadow price;
- the specific market participants being studied should be representative of the target populations to be affected by the rulemaking under consideration;
- a valid research design and framework for analysis should be adopted. Examples include using data and/or model specifications that include the markets for substitute and complementary goods and services and using reasonably unrestricted functional forms. When specifying substitute and complementary goods, the analysis should preferably be

based on data about the range of alternatives perceived by market participants. If such data are not available, you should adopt plausible assumptions and describe the limitations of the analysis.

- the statistical and econometric models employed should be appropriate for the application and the resulting estimates should be robust in response to plausible changes in model specification and estimation technique; and
- the results should be consistent with economic theory.

You should also determine whether there are multiple revealed-preference studies of the same good or service and whether anything can be learned by comparing the methods, data and findings from different studies. Professional judgment is required to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used in regulatory analysis despite their technical weaknesses (e.g., due to the absence of other evidence), the regulatory analysis should discuss any biases or uncertainties that are likely to arise due to those weaknesses. If a study has major weaknesses, the study should not be used in regulatory analysis.

a. Direct Uses of Market Data

Economists ordinarily consider market prices as the most accurate measure of the marginal value of goods and services to society. In some instances, however, market prices may not reflect the true value of goods and services due to market imperfections or government intervention. If a regulation involves changes to goods or services where the market price is not a good measure of the value to society, you should use an estimate that reflects the shadow price. Suppose a particular air pollutant damages crops. One of the benefits of controlling that pollutant is the value of the crop yield increase as a result of the controls. That value is typically measured by the price of the crop. However, if the price is held above the market price by a government program that affects supply, a value estimate based on this price may not reflect the true benefits of controlling the pollutant. In this case, you should calculate the value to society of the increase in crop yields by estimating the shadow price, which reflects the value to society of the marginal use of the crop. If the marginal use is for exports, you should use the world price. If the marginal use is to add to very large surplus stockpiles, you should use the value of the last units released from storage minus storage cost. If stockpiles are large and growing, the shadow price may be low or even negative.

Other goods whose market prices may not reflect their true value include those whose production or consumption results in substantial (1) positive or negative external effects or (2) transfer payments. For example, the observed market price of gasoline may not reflect marginal social value due to the inclusion of taxes, other government interventions, and negative externalities (e.g., pollution). This shadow price may also be needed for goods whose market price is substantially affected by existing regulations that do not maximize net benefits.

b. Indirect Uses of Market Data

Many goods or attributes of goods that are affected by regulation--such as preserving environmental or cultural amenities--are not traded directly in markets. The value for these

goods or attributes arise both from use and non-use. Estimation of these values is difficult because of the absence of an organized market. However, overlooking or ignoring these values in your regulatory analysis may significantly understate the benefits and/or costs of regulatory action.

“Use values” arise where an individual derives satisfaction from using the resource, either now or in the future. Use values are associated with activities such as swimming, hunting, and hiking where the individual makes use of the natural environment.

“Non-use values” arise where an individual places value on a resource, good or service even though the individual will not use the resource, now or in the future. Non-use value includes bequest and existence values.

General altruism for the health and welfare of others is a closely related concept but may not be strictly considered a “non-use” value.¹⁴ A general concern for the welfare of others should supplement benefits and costs equally; hence, it is not necessary to measure the size of general altruism in regulatory analysis. If there is evidence of selective altruism, it needs to be considered specifically in both benefits and costs.

Some goods and services are indirectly traded in markets, which means that their value is reflected in the prices of related goods and services that are directly traded in markets. Their use values are typically estimated through revealed preference methods. Examples include estimates of the values of environmental amenities derived from travel-cost studies, and hedonic price models that measure differences or changes in the value of real estate. It is important that you utilize revealed preference models that adhere to economic criteria that are consistent with utility maximizing behavior. Also, you should take particular care in designing protocols for reliably estimating the values of these attributes.

4. Stated Preference Methods

Stated Preference Methods (SPM) have been developed and used in the peer-reviewed literature to estimate both “use” and “non-use” values of goods and services. They have also been widely used in regulatory analyses by Federal agencies, in part, because these methods can be creatively employed to address a wide variety of goods and services that are not easy to study through revealed preference methods.

The distinguishing feature of these methods is that hypothetical questions about use or non-use values are posed to survey respondents in order to obtain willingness-to-pay estimates relevant to benefit or cost estimation. Some examples of SPM include contingent valuation, conjoint analysis and risk-tradeoff analysis. The surveys used to obtain the health-utility values used in CEA are similar to stated-preference surveys but do not entail monetary measurement of value. Nevertheless, the principles governing quality stated-preference research, with some obvious exceptions involving monetization, are also relevant in designing quality health-utility research.

¹⁴ See McConnell KE (1997), *Journal of Environmental Economics and Management*, 32, 22-37.

When you are designing or evaluating a stated-preference study, the following principles should be considered:

- the good or service being evaluated should be explained to the respondent in a clear, complete and objective fashion, and the survey instrument should be pre-tested;
- willingness-to-pay questions should be designed to focus the respondent on the reality of budgetary limitations and alerted to the availability of substitute goods and alternative expenditure options;
- the survey instrument should be designed to probe beyond general attitudes (e.g., a "warm glow" effect for a particular use or non-use value) and focus on the magnitude of the respondent's economic valuation;
- the analytic results should be consistent with economic theory using both "internal" (within respondent) and "external" (between respondent) scope tests such as the willingness to pay is larger (smaller) when more (less) of a good is provided;
- the subjects being interviewed should be selected/sampled in a statistically appropriate manner. The sample frame should adequately cover the target population. The sample should be drawn using probability methods in order to generalize the results to the target population;
- response rates should be as high as reasonably possible. Best survey practices should be followed to achieve high response rates. Low response rates increase the potential for bias and raise concerns about the generalizability of the results. If response rates are not adequate, you should conduct an analysis of non-response bias or further study. Caution should be used in assessing the representativeness of the sample based solely on demographic profiles. Statistical adjustments to reduce non-response bias should be undertaken whenever feasible and appropriate;
- the mode of administration of surveys (in-person, phone, mail, computer, internet or multiple modes) should be appropriate in light of the nature of the questions being posed to respondents and the length and complexity of the instrument;
- documentation should be provided about the target population, the sampling frame used and its coverage of the target population, the design of the sample including any stratification or clustering, the cumulative response rate (including response rate at each stage of selection if applicable); the item non-response rate for critical questions; the exact wording and sequence of questions and other information provided to respondents; and the training of interviewers and techniques they employed (as appropriate);
- the statistical and econometric methods used to analyze the collected data should be transparent, well suited for the analysis, and applied with rigor and care.

Professional judgment is necessary to apply these criteria to one or more studies, and thus there is no mechanical formula that can be used to determine whether a particular study is of sufficient quality to justify use in regulatory analysis. When studies are used despite having weaknesses on one or more of these criteria, those weaknesses should be acknowledged in the regulatory analysis, including any resulting biases or uncertainties that are likely to result. If a study has too many weaknesses with unknown consequences for the quality of the data, the study should not be used.

The challenge in designing quality stated-preference studies is arguably greater for non-use values and unfamiliar use values than for familiar goods or services that are traded (directly or indirectly) in market transactions. The good being valued may have little meaning to respondents, and respondents may be forming their valuations for the first time in response to the questions posed. Since these values are effectively constructed by the respondent during the elicitation, the instrument and mode of administration should be rigorously pre-tested to make sure that responses are not simply an artifact of specific features of instrument design and/or mode of administration.

Since SPM generate data from respondents in a hypothetical setting, often on complex and unfamiliar goods, special care is demanded in the design and execution of surveys, analysis of the results, and characterization of the uncertainties. A stated-preference study may be the only way to obtain quantitative information about non-use values, though a number based on a poor quality study is not necessarily superior to no number at all. Non-use values that are not quantified should be presented as an “intangible” benefit or cost.

If both revealed-preference and stated-preference studies that are directly applicable to regulatory analysis are available, you should consider both kinds of evidence and compare the findings. If the results diverge significantly, you should compare the overall size and quality of the two bodies of evidence. Other things equal, you should prefer revealed preference data over stated preference data because revealed preference data are based on actual decisions, where market participants enjoy or suffer the consequences of their decisions. This is not generally the case for respondents in stated preference surveys, where respondents may not have sufficient incentives to offer thoughtful responses that are more consistent with their preferences or may be inclined to bias their responses for one reason or another.

5. Benefit-Transfer Methods

It is often preferable to collect original data on revealed preference or stated preference to support regulatory analysis. Yet conducting an original study may not be feasible due to the time and expense involved. One alternative to conducting an original study is the use of “benefit transfer” methods. (The transfer may involve cost determination as well). The practice of “benefit transfer” began with transferring existing estimates obtained from indirect market and stated preference studies to new contexts (i.e., the context posed by the rulemaking). The principles that guide transferring estimates from indirect market and stated preference studies should apply to direct market studies as well.

Although benefit-transfer can provide a quick, low-cost approach for obtaining desired monetary values, the methods are often associated with uncertainties and potential biases of unknown magnitude. It should therefore be treated as a last-resort option and not used without explicit justification.

In conducting benefit transfer, the first step is to specify the value to be estimated for the rulemaking. You should identify the relevant measure of the policy change at this initial stage. For instance, you can derive the relevant willingness-to-pay measure by specifying an indirect utility function. This identification allows you to “zero in” on key aspects of the benefit transfer.

The next step is to identify appropriate studies to conduct benefit transfer. In selecting transfer studies for either point transfers or function transfers, you should base your choices on the following criteria:

- The selected studies should be based on adequate data, sound and defensible empirical methods and techniques.
- The selected studies should document parameter estimates of the valuation function.
- The study context and policy context should have similar populations (e.g., demographic characteristics). The market size (e.g., target population) between the study site and the policy site should be similar. For example, a study valuing water quality improvement in Rhode Island should not be used to value policy that will affect water quality throughout the United States.
- The good, and the magnitude of change in that good, should be similar in the study and policy contexts.
- The relevant characteristics of the study and the policy contexts should be similar. For example, the effects examined in the original study should be “reversible” or “irreversible” to a degree that is similar to the regulatory actions under consideration.
- The distribution of property rights should be similar so that the analysis uses the same welfare measure. If the property rights in the study context support the use of WTA measures while the rights in the rulemaking context support the use of WTP measures, benefit transfer is not appropriate.
- The availability of substitutes across study and policy contexts should be similar.

If you can choose between transferring a function or a point estimate, you should transfer the entire demand function (referred to as benefit function transfer) rather than adopting a single point estimate (referred to as benefit point transfer).¹⁵

Finally, you should not use benefit transfer in estimating benefits if:

- resources are unique or have unique attributes. For example, if a policy change affects snowmobile use in Yellowstone National Park, then a study valuing snowmobile use in the state of Michigan should not be used to value changes in snowmobile use in the Yellowstone National Park.
- If the study examines a resource that is unique or has unique attributes, you should not transfer benefit estimates or benefit functions to value a different resource and vice versa. For example, if a study values visibility improvements at the Grand Canyon, these results should not be used to value visibility improvements in urban areas.
- There are significant problems with applying an “*ex ante*” valuation estimate to an “*ex post*” policy context. If a policy yields a significant change in the attributes of the good, you should not use the study estimates to value the change using a benefit transfer approach.
- You also should not use a value developed from a study involving, small marginal

¹⁵ See Loomis JB (1992), *Water Resources Research*, 28(3), 701-705 and Kirchoff, S, Colby, BG, and LaFrance, JT (1997), *Journal of Environmental Economics and Management*, 33, 75-93.

changes in a policy context involving large changes in the quantity of the good.

Clearly, all of these criteria are difficult to meet. However, you should attempt to satisfy as many as possible when choosing studies from the existing economic literature. Professional judgment is required in determining whether a particular transfer is too speculative to use in regulatory analysis.

6. Ancillary Benefits and Countervailing Risks

Your analysis should look beyond the direct benefits and direct costs of your rulemaking and consider any important ancillary benefits and countervailing risks. An ancillary benefit is a favorable impact of the rule that is typically unrelated or secondary to the statutory purpose of the rulemaking (e.g., reduced refinery emissions due to more stringent fuel economy standards for light trucks) while a countervailing risk is an adverse economic, health, safety, or environmental consequence that occurs due to a rule and is not already accounted for in the direct cost of the rule (e.g., adverse safety impacts from more stringent fuel-economy standards for light trucks).

You should begin by considering and perhaps listing the possible ancillary benefits and countervailing risks. However, highly speculative or minor consequences may not be worth further formal analysis. Analytic priority should be given to those ancillary benefits and countervailing risks that are important enough to potentially change the rank ordering of the main alternatives in the analysis. In some cases the mere consideration of these secondary effects may help in the generation of a superior regulatory alternative with strong ancillary benefits and fewer countervailing risks. For instance, a recent study suggested that weight-based, fuel-economy standards could achieve energy savings with fewer safety risks and employment losses than would occur under the current regulatory structure.

Like other benefits and costs, an effort should be made to quantify and monetize ancillary benefits and countervailing risks. If monetization is not feasible, quantification should be attempted through use of informative physical units. If both monetization and quantification are not feasible, then these issues should be presented as non-quantified benefits and costs. The same standards of information and analysis quality that apply to direct benefits and costs should be applied to ancillary benefits and countervailing risks.

One way to combine ancillary benefits and countervailing risks is to evaluate these effects separately and then put both of these effects on the benefits side, not on the cost side. Although it is theoretically appropriate to include disbenefits on the cost side, legal and programmatic considerations generally support subtracting the disbenefits from direct benefits.

7. Methods for Treating Non-Monetized Benefits and Costs

Sound quantitative estimates of benefits and costs, where feasible, are preferable to qualitative descriptions of benefits and costs because they help decision makers understand the magnitudes of the effects of alternative actions. However, some important benefits and costs (e.g., privacy protection) may be inherently too difficult to quantify or monetize given current

data and methods. You should carry out a careful evaluation of non-quantified benefits and costs. Some authorities¹⁶ refer to these non-monetized and non-quantified effects as “intangible”.

a. Benefits and Costs that are Difficult to Monetize

You should monetize quantitative estimates whenever possible. Use sound and defensible values or procedures to monetize benefits and costs, and ensure that key analytical assumptions are defensible. If monetization is impossible, explain why and present all available quantitative information. For example, if you can quantify but cannot monetize increases in water quality and fish populations resulting from water quality regulation, you can describe benefits in terms of stream miles of improved water quality for boaters and increases in game fish populations for anglers. You should describe the timing and likelihood of such effects and avoid double-counting of benefits when estimates of monetized and physical effects are mixed in the same analysis.

b. Benefits and Costs that are Difficult to Quantify

If you are not able to quantify the effects, you should present any relevant quantitative information along with a description of the unquantified effects, such as ecological gains, improvements in quality of life, and aesthetic beauty. You should provide a discussion of the strengths and limitations of the qualitative information. This should include information on the key reason(s) why they cannot be quantified. In one instance, you may know with certainty the magnitude of a risk to which a substantial, but unknown, number of individuals are exposed. In another instance, the existence of a risk may be based on highly speculative assumptions, and the magnitude of the risk may be unknown.

For cases in which the unquantified benefits or costs affect a policy choice, you should provide a clear explanation of the rationale behind the choice. Such an explanation could include detailed information on the nature, timing, likelihood, location, and distribution of the unquantified benefits and costs. Also, please include a summary table that lists all the unquantified benefits and costs, and use your professional judgment to highlight (e.g., with categories or rank ordering) those that you believe are most important (e.g., by considering factors such as the degree of certainty, expected magnitude, and reversibility of effects).

While the focus is often placed on difficult to quantify benefits of regulatory action, some costs are difficult to quantify as well. Certain permitting requirements (e.g., EPA's New Source Review program) restrict the decisions of production facilities to shift to new products and adopt innovative methods of production. While these programs may impose substantial costs on the economy, it is very difficult to quantify and monetize these effects. Similarly, regulations that establish emission standards for recreational vehicles, like motor bikes, may adversely affect the performance of the vehicles in terms of driveability and 0 to 60 miles per hour acceleration. Again, the cost associated with the loss of these attributes may be difficult to quantify and monetize. They need to be analyzed qualitatively.

¹⁶ Mishan EJ (1994), *Cost-Benefit Analysis*, fourth edition, Routledge, New York.

8. Monetizing Health and Safety Benefits and Costs

We expect you to provide a benefit-cost analysis of major health and safety rulemakings in addition to a CEA. The BCA provides additional insight because (a) it provides some indication of what the public is willing to pay for improvements in health and safety and (b) it offers additional information on preferences for health using a different research design than is used in CEA. Since the health-preference methods used to support CEA and BCA have some different strengths and drawbacks, it is important that you provide decision makers with both perspectives.

In monetizing health benefits, a WTP measure is the conceptually appropriate measure as compared to other alternatives (e.g., cost of illness or lifetime earnings), in part because it attempts to capture pain and suffering and other quality-of-life effects. Using the WTP measure for health and safety allows you to directly compare your results to the other benefits and costs in your analysis, which will typically be based on WTP.

If well-conducted revealed-preference studies of relevant health and safety risks are available, you should consider using them in developing your monetary estimates. If appropriate revealed-preference data are not available, you should use valid and relevant data from stated-preference studies. You will need to use your professional judgment when you are faced with limited information on revealed preference studies and substantial information based on stated preference studies.

A key advantage of stated-preference and health-utility methods compared to revealed preference methods is that they can be tailored to address the ranges of probabilities, types of health risks and specific populations affected by your rule. In many rulemakings there will be no relevant information from revealed-preference studies. In this situation you should consider commissioning a stated-preference study or using values from published stated-preference studies. For the reasons discussed previously, you should be cautious about using values from stated-preference studies and describe in the analysis the drawbacks of this approach.

a. Nonfatal Health and Safety Risks

With regard to nonfatal health and safety risks, there is enormous diversity in the nature and severity of impaired health states. A traumatic injury that can be treated effectively in the emergency room without hospitalization or long-term care is different from a traumatic injury resulting in paraplegia. Severity differences are also important in evaluation of chronic diseases. A severe bout of bronchitis, though perhaps less frequent, is far more painful and debilitating than the more frequent bouts of mild bronchitis. The duration of an impaired health state, which can range from a day or two to several years or even a lifetime (e.g., birth defects inducing mental retardation), need to be considered carefully. Information on both the severity and duration of an impaired health state is necessary before the task of monetization can be performed.

When monetizing nonfatal health effects, it is important to consider two components: (1) the private demand for prevention of the nonfatal health effect, to be represented by the

preferences of the target population at risk, and (2) the net financial externalities associated with poor health such as net changes in public medical costs and any net changes in economic production that are not experienced by the target population. Revealed-preference or stated-preference studies are necessary to estimate the private demand; health economics data from published sources can typically be used to estimate the financial externalities caused by changes in health status. If you use literature values to monetize nonfatal health and safety risks, it is important to make sure that the values you have selected are appropriate for the severity and duration of health effects to be addressed by your rule.

If data are not available to support monetization, you might consider an alternative approach that makes use of health-utility studies. Although the economics literature on the monetary valuation of impaired health states is growing, there is a much larger clinical literature on how patients, providers and community residents value diverse health states. This literature typically measures health utilities based on the standard gamble, the time tradeoff or the rating scale methods. This health utility information may be combined with known monetary values for well-defined health states to estimate monetary values for a wide range of health states of different severity and duration. If you use this approach, you should be careful to acknowledge your assumptions and the limitations of your estimates.

b. Fatality Risks

Since agencies often design health and safety regulation to reduce risks to life, evaluation of these benefits can be the key part of the analysis. A good analysis must present these benefits clearly and show their importance. Agencies may choose to monetize these benefits. The willingness-to-pay approach is the best methodology to use if reductions in fatality risk are monetized.

Some describe the monetized value of small changes in fatality risk as the "value of statistical life" (VSL) or, less precisely, the "value of a life." The latter phrase can be misleading because it suggests erroneously that the monetization exercise tries to place a "value" on individual lives. You should make clear that these terms refer to the measurement of willingness to pay for reductions in only small risks of premature death. They have no application to an identifiable individual or to very large reductions in individual risks. They do not suggest that any individual's life can be expressed in monetary terms. Their sole purpose is to help describe better the likely benefits of a regulatory action.

Confusion about the term "statistical life" is also widespread. This term refers to the sum of risk reductions expected in a population. For example, if the annual risk of death is reduced by one in a million for each of two million people, that is said to represent two "statistical lives" extended per year ($2 \text{ million people} \times 1/1,000,000 = 2$). If the annual risk of death is reduced by one in 10 million for each of 20 million people, that also represents two statistical lives extended.

The adoption of a value for the projected reduction in the risk of premature mortality is the subject of continuing discussion within the economic and public policy analysis community. A considerable body of academic literature is available on this subject. This literature involves either explicit or implicit valuation of fatality risks, and generally involves the use of estimates of

VSL from studies on wage compensation for occupational hazards (which generally are in the range of 10^{-4} annually), on consumer product purchase and use decisions, or from an emerging literature using stated preference approaches. A substantial majority of the resulting estimates of VSL vary from roughly \$1 million to \$10 million per statistical life.¹⁷

There is a continuing debate within the economic and public policy analysis community on the merits of using a single VSL for all situations versus adjusting the VSL estimates to reflect the specific rule context. A variety of factors have been identified, including whether the mortality risk involves sudden death, the fear of cancer, and the extent to which the risk is voluntarily incurred.¹⁸ The consensus of EPA's recent Science Advisory Board (SAB) review of this issue was that the available literature does not support adjustments of VSL for most of these factors. The panel did conclude that it was appropriate to adjust VSL to reflect changes in income and any time lag in the occurrence of adverse health effects.

The age of the affected population has also been identified as an important factor in the theoretical literature. However, the empirical evidence on age and VSL is mixed. In light of the continuing questions over the effect of age on VSL estimates, you should not use an age-adjustment factor in an analysis using VSL estimates.¹⁹

Another way that has been used to express reductions in fatality risks is to use the life expectancy method, the "value of statistical life-years (VSLY) extended." If a regulation protects individuals whose average remaining life expectancy is 40 years, a risk reduction of one fatality is expressed as "40 life-years extended." Those who favor this alternative approach emphasize that the value of a statistical life is not a single number relevant for all situations. In particular, when there are significant differences between the effect on life expectancy for the population affected by a particular health risk and the populations studied in the labor market studies, they prefer to adopt a VSLY approach to reflect those differences. You should consider providing estimates of both VSL and VSLY, while recognizing the developing state of knowledge in this area.

Longevity may be only one of a number of relevant considerations pertaining to the rule. You should keep in mind that regulations with greater numbers of life-years extended are not necessarily better than regulations with fewer numbers of life-years extended. In any event, when you present estimates based on the VSLY method, you should adopt a larger VSLY estimate for senior citizens because senior citizens face larger overall health risks from all causes and they may have accumulated savings to spend on their health and safety.²⁰

The valuation of fatality risk reduction is an evolving area in both results and methodology. Hence, you should utilize valuation methods that you consider appropriate for the

¹⁷ See Viscusi WK and Aldy JE, *Journal of Risk and Uncertainty* (forthcoming) and Mrozek JR and Taylor LO (2002), *Journal of Policy Analysis and Management*, 21(2), 253-270.

¹⁸ Distinctions between "voluntary" and "involuntary" should be treated with care. Risks are best considered to fall within a continuum from "voluntary" to "involuntary" with very few risks at either end of this range. These terms are also related to differences in the cost of avoiding risks.

¹⁹ Graham JD (2003), Memorandum to the President's Management Council, Benefit-Cost Methods and Lifesaving Rules. This memorandum can be found at http://www.whitehouse.gov/omb/inforeg/pmc_benefit_cost_memo.pdf

²⁰ Office of Information and Regulatory Affairs, OMB, Memorandum to the President's Management Council, *ibid*.

regulatory circumstances. Since the literature-based VSL estimates may not be entirely appropriate for the risk being evaluated (e.g., the use of occupational risk premia to value reductions in risks from environmental hazards), you should explain your selection of estimates and any adjustments of the estimates to reflect the nature of the risk being evaluated. You should present estimates based on alternative approaches, and if you monetize mortality risk reduction, you should do so on a consistent basis to the extent feasible. You should clearly indicate the methodology used and document your choice of a particular methodology. You should explain any significant deviations from the prevailing state of knowledge. If you use different methodologies in different rules, you should clearly disclose the fact and explain your choices.

c. Valuation of Reductions in Health and Safety Risks to Children

The valuation of health outcomes for children and infants poses special challenges. It is rarely feasible to measure a child's willingness to pay for health improvement and an adult's concern for his or her own health is not necessarily relevant to valuation of child health. For example, the wage premiums demanded by workers to accept hazardous jobs are not readily transferred to rules that accomplish health gains for children.

There are a few studies that examine parental willingness to pay to invest in health and safety for their children. Some of these studies suggest that parents may value children's health more strongly than their own health. Although this parental perspective is a promising research strategy, it may need to be expanded to include a societal interest in child health and safety.

Where the primary objective of a rule is to reduce the risk of injury, disease or mortality among children, you should conduct a cost-effectiveness analysis of the rule. You may also develop a benefit-cost analysis to the extent that valid monetary values can be assigned to the primary expected health outcomes. For rules where health gains are expected among both children and adults and you decide to perform a benefit-cost analysis, the monetary values for children should be at least as large as the values for adults (for the same probabilities and outcomes) unless there is specific and compelling evidence to suggest otherwise.²¹

Discount Rates

Benefits and costs do not always take place in the same time period. When they do not, it is incorrect simply to add all of the expected net benefits or costs without taking account of when the actually occur. If benefits or costs are delayed or otherwise separated in time from each other, the difference in timing should be reflected in your analysis.

As a first step, you should present the annual time stream of benefits and costs expected to result from the rule, clearly identifying when the benefits and costs are expected to occur. The beginning point for your stream of estimates should be the year in which the final rule will begin to have effects, even if that is expected to be some time in the future. The ending point should be far enough in the future to encompass all the significant benefits and costs likely to result from the rule.

²¹ For more information, see Dockins C., Jenkins RR, Owens N, Simon NB, and Wiggins LB (2002), *Risk Analysis*, 22(2), 335-346.

In presenting the stream of benefits and costs, it is important to measure them in constant dollars to avoid the misleading effects of inflation in your estimates. If the benefits and costs are initially measured in prices reflecting expected future inflation, you can convert them to constant dollars by dividing through by an appropriate inflation index, one that corresponds to the inflation rate underlying the initial estimates of benefits or costs.

1. The Rationale for Discounting

Once these preliminaries are out of the way, you can begin to adjust your estimates for differences in timing. (This is a separate calculation from the adjustment needed to remove the effects of future inflation.) Benefits or costs that occur sooner are generally more valuable. The main rationales for the discounting of future impacts are:

- (a) Resources that are invested will normally earn a positive return, so current consumption is more expensive than future consumption, since you are giving up that expected return on investment when you consume today.
- (b) Postponed benefits also have a cost because people generally prefer present to future consumption. They are said to have positive time preference.
- (c) Also, if consumption continues to increase over time, as it has for most of U.S. history, an increment of consumption will be less valuable in the future than it would be today, because the principle of diminishing marginal utility implies that as total consumption increases, the value of a marginal unit of consumption tends to decline.

There is wide agreement with point (a). Capital investment is productive, but that point is not sufficient by itself to explain positive interest rates and observed saving behavior. To understand these phenomena, points (b) and (c) are also necessary. If people are really indifferent between consumption now and later, then they should be willing to forgo current consumption in order to consume an equal or slightly greater amount in the future. That would cause saving rates and investment to rise until interest rates were driven to zero and capital was no longer productive. As long as we observe positive interest rates and saving rates below 100 percent, people must be placing a higher value on current consumption than on future consumption.

To reflect this preference, a discount factor should be used to adjust the estimated benefits and costs for differences in timing. The further in the future the benefits and costs are expected to occur, the more they should be discounted. The discount factor can be calculated given a discount rate. The formula is $1 / (1 + \text{the discount rate})^t$ where "t" measures the number of years in the future that the benefits or costs are expected to occur. Benefits or costs that have been adjusted in this way are called "discounted present values" or simply "present values". When, and only when, the estimated benefits and costs have been discounted, they can be added to determine the overall value of net benefits.

2. Real Discount Rates of 3 Percent and 7 Percent

OMB's basic guidance on the discount rate is provided in OMB Circular A-94 (<http://www.whitehouse.gov/omb/circulars/index.html>). This Circular points out that the analytically preferred method of handling temporal differences between benefits and costs is to adjust all the benefits and costs to reflect their value in equivalent units of consumption and to discount them at the rate consumers and savers would normally use in discounting future consumption benefits. This is sometimes called the "shadow price" approach to discounting because doing such calculations requires you to value benefits and costs using shadow prices, especially for capital goods, to correct for market distortions. These shadow prices are not well established for the United States. Furthermore, the distribution of impacts from regulations on capital and consumption are not always well known. Consequently, any agency that wishes to tackle this challenging analytical task should check with OMB before proceeding.

As a default position, OMB Circular A-94 states that a real discount rate of 7 percent should be used as a base-case for regulatory analysis. The 7 percent rate is an estimate of the average before-tax rate of return to private capital in the U.S. economy. It is a broad measure that reflects the returns to real estate and small business capital as well as corporate capital. It approximates the opportunity cost of capital, and it is the appropriate discount rate whenever the main effect of a regulation is to displace or alter the use of capital in the private sector. OMB revised Circular A-94 in 1992 after extensive internal review and public comment. In a recent analysis, OMB found that the average rate of return to capital remains near the 7 percent rate estimated in 1992. Circular A-94 also recommends using other discount rates to show the sensitivity of the estimates to the discount rate assumption.

Economic distortions, including taxes on capital, create a divergence between the rate of return that savers earn and the private rate of return to capital. This divergence persists despite the tendency for capital to flow to where it can earn the highest rate of return. Although market forces will push after-tax rates of return in different sectors of the economy toward equality, that process will not equate pre-tax rates of return when there are differences in the tax treatment of investment. Corporate capital, in particular, pays an additional layer of taxation, the corporate income tax, which requires it to earn a higher pre-tax rate of return in order to provide investors with similar after-tax rates of return compared with non-corporate investments. The pre-tax rates of return better measure society's gains from investment. Since the rates of return on capital are higher in some sectors of the economy than others, the government needs to be sensitive to possible impacts of regulatory policy on capital allocation.

The effects of regulation do not always fall exclusively or primarily on the allocation of capital. When regulation primarily and directly affects private consumption (e.g., through higher consumer prices for goods and services), a lower discount rate is appropriate. The alternative most often used is sometimes called the "social rate of time preference." This simply means the rate at which "society" discounts future consumption flows to their present value. If we take the rate that the average saver uses to discount future consumption as our measure of the social rate of time preference, then the real rate of return on long-term government debt may provide a fair approximation. Over the last thirty years, this rate has averaged around 3 percent in real terms on a pre-tax basis. For example, the yield on 10-year Treasury notes has averaged 8.1 percent since

1973 while the average annual rate of change in the CPI over this period has been 5.0 percent, implying a real 10-year rate of 3.1 percent.

For regulatory analysis, you should provide estimates of net benefits using both 3 percent and 7 percent. An example of this approach is EPA's analysis of its 1998 rule setting both effluent limits for wastewater discharges and air toxic emission limits for pulp and paper mills. In this analysis, EPA developed its present-value estimates using real discount rates of 3 and 7 percent applied to benefit and cost streams that extended forward for 30 years. You should present a similar analysis in your own work.

In some instances, if there is reason to expect that the regulation will cause resources to be reallocated away from private investment in the corporate sector, then the opportunity cost may lie outside the range of 3 to 7 percent. For example, the average real rate of return on corporate capital in the United States was approximately 10 percent in the 1990s, returning to the same level observed in the 1950s and 1960s. If you are uncertain about the nature of the opportunity cost, then you should present benefit and cost estimates using a higher discount rate as a further sensitivity analysis as well as using the 3 and 7 percent rates.

3. Time Preference for Health-Related Benefits and Costs

When future benefits or costs are health-related, some have questioned whether discounting is appropriate, since the rationale for discounting money may not appear to apply to health. It is true that lives saved today cannot be invested in a bank to save more lives in the future. But the resources that would have been used to save those lives can be invested to earn a higher payoff in future lives saved. People have been observed to prefer health gains that occur immediately to identical health gains that occur in the future. Also, if future health gains are not discounted while future costs are, then the following perverse result occurs: an attractive investment today in future health improvement can always be made more attractive by delaying the investment. For such reasons, there is a professional consensus that future health effects, including both benefits and costs, should be discounted at the same rate. This consensus applies to both BCA and CEA.

A common challenge in health-related analysis is to quantify the time lag between when a rule takes effect and when the resulting physical improvements in health status will be observed in the target population. In such situations, you must carefully consider the timing of health benefits before performing present-value calculations. It is not reasonable to assume that all of the benefits of reducing chronic diseases such as cancer and cardiovascular disease will occur immediately when the rule takes effect. For rules addressing traumatic injury, this lag period may be short. For chronic diseases it may take years or even decades for a rule to induce its full beneficial effects in the target population.

When a delay period between exposure to a toxin and increased probability of disease is likely (a so-called latency period), a lag between exposure reduction and reduced probability of disease is also likely. This latter period has sometimes been referred to as a "cessation lag," and it may or may not be of the same duration as the latency period. As a general matter, cessation lags will only apply to populations with at least some high-level exposure (e.g., before the rule

takes effect). For populations with no such prior exposure, such as those born after the rule takes effect, only the latency period will be relevant.

Ideally, your exposure-risk model would allow calculation of reduced risk for each year following exposure cessation, accounting for total cumulative exposure and age at the time of exposure reduction. The present-value benefits estimate could then reflect an appropriate discount factor for each year's risk reduction. Recent analyses of the cancer benefits stemming from reduction in public exposure to radon in drinking water have adopted this approach. They were supported by formal risk-assessment models that allowed estimates of the timing of lung cancer incidence and mortality to vary in response to different radon exposure levels.²²

In many cases, you will not have the benefit of such detailed risk assessment modeling. You will need to use your professional judgment as to the average cessation lag for the chronic diseases affected by your rule. In situations where information exists on latency but not on cessation lags, it may be reasonable to use latency as a proxy for the cessation lag, unless there is reason to believe that the two are different. When the average lag time between exposures and disease is unknown, a range of plausible alternative values for the time lag should be used in your analysis.

4. Intergenerational Discounting

Special ethical considerations arise when comparing benefits and costs across generations. Although most people demonstrate time preference in their own consumption behavior, it may not be appropriate for society to demonstrate a similar preference when deciding between the well-being of current and future generations. Future citizens who are affected by such choices cannot take part in making them, and today's society must act with some consideration of their interest.

One way to do this would be to follow the same discounting techniques described above and supplement the analysis with an explicit discussion of the intergenerational concerns (how future generations will be affected by the regulatory decision). Policymakers would be provided with this additional information without changing the general approach to discounting.

Using the same discount rate across generations has the advantage of preventing time-inconsistency problems. For example, if one uses a lower discount rate for future generations, then the evaluation of a rule that has short-term costs and long-term benefits would become more favorable merely by waiting a year to do the analysis. Further, using the same discount rate across generations is attractive from an ethical standpoint. If one expects future generations to be better off, then giving them the advantage of a lower discount rate would in effect transfer resources from poorer people today to richer people tomorrow.

Some believe, however, that it is ethically impermissible to discount the utility of future generations. That is, government should treat all generations equally. Even under this approach,

²² Committee on Risk Assessment of Exposure to Radon in Drinking Water, Board on Radiation Effects Research, Commission on Life Sciences (1996), *Risk Assessment of Radon in Drinking Water*, National Research Council, National Academy Press, Washington, DC.

it would still be correct to discount future costs and consumption benefits generally (perhaps at a lower rate than for intragenerational analysis), due to the expectation that future generations will be wealthier and thus will value a marginal dollar of benefits or costs by less than those alive today. Therefore, it is appropriate to discount future benefits and costs relative to current benefits and costs, even if the welfare of future generations is not being discounted. Estimates of the appropriate discount rate appropriate in this case, from the 1990s, ranged from 1 to 3 percent per annum.²³

A second reason for discounting the benefits and costs accruing to future generations at a lower rate is increased uncertainty about the appropriate value of the discount rate, the longer the horizon for the analysis. Private market rates provide a reliable reference for determining how society values time within a generation, but for extremely long time periods no comparable private rates exist. As explained by Martin Weitzman²⁴, in the limit for the deep future, the properly averaged certainty-equivalent discount factor (i.e., $1/[1+r]^t$) corresponds to the minimum discount rate having any substantial positive probability. From today's perspective, the only relevant limiting scenario is the one with the lowest discount rate – all of the other states at the far-distant time are relatively much less important because their expected present value is so severely reduced by the power of compounding at a higher rate.

If your rule will have important intergenerational benefits or costs you might consider a further sensitivity analysis using a lower but positive discount rate in addition to calculating net benefits using discount rates of 3 and 7 percent.

5. Time Preference for Non-Monetized Benefits and Costs

Differences in timing should be considered even for benefits and costs that are not expressed in monetary units, including health benefits. The timing differences can be handled through discounting. EPA estimated cost-effectiveness in its 1998 rule, "Control of Emissions from Nonroad Diesel Engines," by discounting both the monetary costs and the non-monetized emission reduction benefits over the expected useful life of the engines at the 7 percent real rate recommended in OMB Circular A-94.

Alternatively, it may be possible in some cases to avoid discounting non-monetized benefits. If the expected flow of benefits begins as soon as the cost is incurred and is expected to be constant over time, then annualizing the cost stream is sufficient, and further discounting of benefits is unnecessary. Such an analysis might produce an estimate of the annualized cost per ton of reduced emissions of a pollutant.

6. The Internal Rate of Return

The internal rate of return is the discount rate that sets the net present value of the discounted benefits and costs equal to zero. The internal rate of return does not generally

²³ Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

²⁴ Weitzman ML In Portney PR and Weyant JP, eds. (1999), *Discounting and Intergenerational Equity*, Resources for the Future, Washington, DC.

provide an acceptable decision criterion, and regulations with the highest internal rate of return are not necessarily the most beneficial. Nevertheless, it does provide useful information and for many it will offer a meaningful indication of regulation's impact. You should consider including the internal rate of return implied by your regulatory analysis along with other information about discounted net present values.

Other Key Considerations

1. Other Benefit and Cost Considerations

You should include these effects in your analysis and provide estimates of their monetary values when they are significant:

- Private-sector compliance costs and savings;
- Government administrative costs and savings;
- Gains or losses in consumers' or producers' surpluses;
- Discomfort or inconvenience costs and benefits; and
- Gains or losses of time in work, leisure and/or commuting/travel settings.

Estimates of benefits and costs should be based on credible changes in technology over time. For example, retrospective studies may provide evidence that "learning" will likely reduce the cost of regulation in future years. The weight you give to a study of past rates of cost savings resulting from innovation (including "learning curve" effects) should depend on both its timeliness and direct relevance to the processes affected by the regulatory alternative under consideration. In addition, you should take into account cost-saving innovations that result from a shift to regulatory performance standards and incentive-based policies. On the other hand, significant costs may result from a slowing in the rate of innovation or of adoption of new technology due to delays in the regulatory approval process or the setting of more stringent standards for new facilities than existing ones. In some cases agencies are limited under statute to consider only technologies that have been demonstrated to be feasible. In these situations, it may be useful to estimate costs and cost savings assuming a wider range of technical possibilities.

When characterizing technology changes over time, you should assess the likely technology changes that would have occurred in the absence of the regulatory action (technology baseline). Technologies change over time in both reasonably functioning markets and imperfect markets. If you assume that technology will remain unchanged in the absence of regulation when technology changes are likely, then your analysis will over-state both the benefits and costs attributable to the regulation.

Occasionally, cost savings or other forms of benefits accrue to parties affected by a rule who also bear its costs. For example, a requirement that engine manufacturers reduce emissions from engines may lead to technologies that improve fuel economy. These fuel savings will normally accrue to the engine purchasers, who also bear the costs of the technologies. There is no apparent market failure with regard to the market value of fuel saved because one would expect that consumers would be willing to pay for increased fuel economy that exceeded the cost

of providing it. When these cost savings are substantial, and particularly when you estimate them to be greater than the cost associated with achieving them, you should examine and discuss why market forces would not accomplish these gains in the absence of regulation. As a general matter, any direct costs that are averted as a result of a regulatory action should be monetized wherever possible and either added to the benefits or subtracted from the costs of that alternative.

2. The Difference between Costs (or Benefits) and Transfer Payments

Distinguishing between real costs and transfer payments is an important, but sometimes difficult, problem in cost estimation. Benefit and cost estimates should reflect real resource use. Transfer payments are monetary payments from one group to another that do not affect total resources available to society. A regulation that restricts the supply of a good, causing its price to rise, produces a transfer from buyers to sellers. The net reduction in the total surplus (consumer plus producer) is a real cost to society, but the transfer from buyers to sellers resulting from a higher price is not a real cost since the net reduction automatically accounts for the transfer from buyers to sellers. However, transfers from the United States to other nations should be included as costs, and transfers from other nations to the United States as benefits, as long as the analysis is conducted from the United States perspective.

You should not include transfers in the estimates of the benefits and costs of a regulation. Instead, address them in a separate discussion of the regulation's distributional effects. Examples of transfer payments include the following:

- Scarcity rents and monopoly profits
- Insurance payments
- Indirect taxes and subsidies

Treatment of Uncertainty

The precise consequences (benefits and costs) of regulatory options are not always known for certain, but the probability of their occurrence can often be developed. The important uncertainties connected with your regulatory decisions need to be analyzed and presented as part of the overall regulatory analysis. You should begin your analysis of uncertainty at the earliest possible stage in developing your analysis. You should consider both the statistical variability of key elements underlying the estimates of benefits and costs (for example, the expected change in the distribution of automobile accidents that might result from a change in automobile safety standards) and the incomplete knowledge about the relevant relationships (for example, the uncertain knowledge of how some economic activities might affect future climate change).²⁵ By assessing the sources of uncertainty and the way in which benefit and cost estimates may be affected under plausible assumptions, you can shape your analysis to inform decision makers and the public about the effects and the uncertainties of alternative regulatory actions.

²⁵ In some contexts, the word "variability" is used as a synonym for statistical variation that can be described by a theoretically valid distribution function, whereas "uncertainty" refers to a more fundamental lack of knowledge. Throughout this discussion, we use the term "uncertainty" to refer to both concepts.

The treatment of uncertainty must be guided by the same principles of full disclosure and transparency that apply to other elements of your regulatory analysis. Your analysis should be credible, objective, realistic, and scientifically balanced.²⁶ Any data and models that you use to analyze uncertainty should be fully identified. You should also discuss the quality of the available data used. Inferences and assumptions used in your analysis should be identified, and your analytical choices should be explicitly evaluated and adequately justified. In your presentation, you should delineate the strengths of your analysis along with any uncertainties about its conclusions. Your presentation should also explain how your analytical choices have affected your results.

In some cases, the level of scientific uncertainty may be so large that you can only present discrete alternative scenarios without assessing the relative likelihood of each scenario quantitatively. For instance, in assessing the potential outcomes of an environmental effect, there may be a limited number of scientific studies with strongly divergent results. In such cases, you might present results from a range of plausible scenarios, together with any available information that might help in qualitatively determining which scenario is most likely to occur.

When uncertainty has significant effects on the final conclusion about net benefits, your agency should consider additional research prior to rulemaking. The costs of being wrong may outweigh the benefits of a faster decision. This is true especially for cases with irreversible or large upfront investments. If your agency decides to proceed with rulemaking, you should explain why the costs of developing additional information—including any harm from delay in public protection—exceed the value of that information.

For example, when the uncertainty is due to a lack of data, you might consider deferring the decision, as an explicit regulatory alternative, pending further study to obtain sufficient data.²⁷ Delaying a decision will also have costs, as will further efforts at data gathering and analysis. You will need to weigh the benefits of delay against these costs in making your decision. Formal tools for assessing the value of additional information are now well developed in the applied decision sciences and can be used to help resolve this type of complex regulatory question.

“Real options” methods have also formalized the valuation of the added flexibility inherent in delaying a decision. As long as taking time will lower uncertainty, either passively or actively through an investment in information gathering, and some costs are irreversible, such as the potential costs of a sunk investment, a benefit can be assigned to the option to delay a decision. That benefit should be considered a cost of taking immediate action versus the alternative of delaying that action pending more information. However, the burdens of delay—including any harm to public health, safety, and the environment—need to be analyzed carefully.

1. Quantitative Analysis of Uncertainty

²⁶ When disseminating information, agencies should follow their own information quality guidelines, issued in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002).

²⁷ Clemen RT (1996), *Making Hard Decisions: An Introduction to Decision Analysis*, second edition, Duxbury Press, Pacific Grove.

Examples of quantitative analysis, broadly defined, would include formal estimates of the probabilities of environmental damage to soil or water, the possible loss of habitat, or risks to endangered species as well as probabilities of harm to human health and safety. There are also uncertainties associated with estimates of economic benefits and costs, such as the cost savings associated with increased energy efficiency. Thus, your analysis should include two fundamental components: a quantitative analysis characterizing the probabilities of the relevant outcomes and an assignment of economic value to the projected outcomes. It is essential that both parts be conceptually consistent. In particular, the quantitative analysis should be conducted in a way that permits it to be applied within a more general analytical framework, such as benefit-cost analysis. Similarly, the general framework needs to be flexible enough to incorporate the quantitative analysis without oversimplifying the results. For example, you should address explicitly the implications for benefits and costs of any probability distributions developed in your analysis.

As with other elements of regulatory analysis, you will need to balance thoroughness with the practical limits on your analytical capabilities. Your analysis does not have to be exhaustive, nor is it necessary to evaluate each alternative at every step. Attention should be devoted to first resolving or studying the uncertainties that have the largest potential effect on decision making. Many times these will be the largest sources of uncertainties. In the absence of adequate data, you will need to make assumptions. These should be clearly identified and consistent with the relevant science. Your analysis should provide sufficient information for decision makers to grasp the degree of scientific uncertainty and the robustness of estimated probabilities, benefits, and costs to changes in key assumptions.

For major rules involving annual economic effects of \$1 billion or more, you should present a formal quantitative analysis of the relevant uncertainties about benefits and costs. In other words, you should try to provide some estimate of the probability distribution of regulatory benefits and costs. In summarizing the probability distributions, you should provide some estimates of the central tendency (e.g., mean and median) along with any other information you think will be useful such as ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Your estimates cannot be more precise than their most uncertain component. Thus, your analysis should report estimates in a way that reflects the degree of uncertainty and not create a false sense of precision. Worst-case or conservative analyses are not usually adequate because they do not convey the complete probability distribution of outcomes, and they do not permit calculation of an expected value of net benefits. In many health and safety rules, economists conducting benefit-cost analyses must rely on formal risk assessments that address a variety of risk management questions such as the baseline risk for the affected population, the safe level of exposure or, the amount of risk to be reduced by various interventions. Because the answers to some of these questions are directly used in benefits analyses, the risk assessment methodology must allow for the determination of expected benefits in order to be comparable to expected costs. This means that conservative assumptions and defaults (whether motivated by science policy or by precautionary instincts), will be incompatible with benefit analyses as they will result in benefit estimates that exceed the expected value. Whenever it is possible to characterize quantitatively the probability distributions, some estimates of expected value (e.g., mean and

median) must be provided in addition to ranges, variances, specified low-end and high-end percentile estimates, and other characteristics of the distribution.

Whenever possible, you should use appropriate statistical techniques to determine a probability distribution of the relevant outcomes. For rules that exceed the \$1 billion annual threshold, a formal quantitative analysis of uncertainty is required. For rules with annual benefits and/or costs in the range from 100 million to \$1 billion, you should seek to use more rigorous approaches with higher consequence rules. This is especially the case where net benefits are close to zero. More rigorous uncertainty analysis may not be necessary for rules in this category if simpler techniques are sufficient to show robustness. You may consider the following analytical approaches that entail increasing levels of complexity:

- Disclose qualitatively the main uncertainties in each important input to the calculation of benefits and costs. These disclosures should address the uncertainties in the data as well as in the analytical results. However, major rules above the \$1 billion annual threshold require a formal treatment.
- Use a numerical sensitivity analysis to examine how the results of your analysis vary with plausible changes in assumptions, choices of input data, and alternative analytical approaches. Sensitivity analysis is especially valuable when the information is lacking to carry out a formal probabilistic simulation. Sensitivity analysis can be used to find “switch points” -- critical parameter values at which estimated net benefits change sign or the low cost alternative switches. Sensitivity analysis usually proceeds by changing one variable or assumption at a time, but it can also be done by varying a combination of variables simultaneously to learn more about the robustness of your results to widespread changes. Again, however, major rules above the \$1 billion annual threshold require a formal treatment.
- Apply a formal probabilistic analysis of the relevant uncertainties – possibly using simulation models and/or expert judgment as revealed, for example, through Delphi methods.²⁸ Such a formal analytical approach is appropriate for complex rules where there are large, multiple uncertainties whose analysis raises technical challenges, or where the effects cascade; it is required for rules that exceed the \$1 billion annual threshold. For example, in the analysis of regulations addressing air pollution, there is uncertainty about the effects of the rule on future emissions, uncertainty about how the change in emissions will affect air quality, uncertainty about how changes in air quality will affect health, and finally uncertainty about the economic and social value of the change in health outcomes. In formal probabilistic assessments, expert solicitation is a useful way to fill key gaps in your ability to assess uncertainty.²⁹ In general, experts can be used to quantify the probability distributions of key parameters and relationships. These solicitations, combined with other sources of data, can be combined in Monte Carlo simulations to derive a probability distribution of benefits and costs. You should

²⁸ The purpose of Delphi methods is to generate suitable information for decision making by eliciting expert judgment. The elicitation is conducted through a survey process which eliminates the interactions between experts. See Morgan MG and Henrion M (1990), *Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis*, Cambridge University Press.

²⁹ Cooke RM (1991), *Experts in Uncertainty: Opinion and Subjective Probability in Science*, Oxford University Press.

pay attention to correlated inputs. Often times, the standard defaults in Monte Carlo and other similar simulation packages assume independence across distributions. Failing to correctly account for correlated distributions of inputs can cause the resultant output uncertainty intervals to be too large, although in many cases the overall effect is ambiguous. You should make a special effort to portray the probabilistic results—in graphs and/or tables—clearly and meaningfully.

New methods may become available in the future. This document is not intended to discourage or inhibit their use, but rather to encourage and stimulate their development.

2. Economic Values of Uncertain Outcomes

In developing benefit and cost estimates, you may find that there are probability distributions of values as well for each of the outcomes. Where this is the case, you will need to combine these probability distributions to provide estimated benefits and costs.

Where there is a distribution of outcomes, you will often find it useful to emphasize summary statistics or figures that can be readily understood and compared to achieve the broadest public understanding of your findings. It is a common practice to compare the “best estimates” of both benefits and costs with those of competing alternatives. These “best estimates” are usually the average or the expected value of benefits and costs. Emphasis on these expected values is appropriate as long as society is “risk neutral” with respect to the regulatory alternatives. While this may not always be the case, you should in general assume “risk neutrality” in your analysis. If you adopt a different assumption on risk preference, you should explain your reasons for doing so.

3. Alternative Assumptions

If benefit or cost estimates depend heavily on certain assumptions, you should make those assumptions explicit and carry out sensitivity analyses using plausible alternative assumptions. If the value of net benefits changes from positive to negative (or vice versa) or if the relative ranking of regulatory options changes with alternative plausible assumptions, you should conduct further analysis to determine which of the alternative assumptions is more appropriate. Because different estimation methods may have hidden assumptions, you should analyze estimation methods carefully to make any hidden assumptions explicit.

F. Specialized Analytical Requirements

In preparing analytical support for your rulemaking, you should be aware that there are a number of analytic requirements imposed by law and Executive Order. In addition to the regulatory analysis requirements of Executive Order 12866, you should also consider whether your rule will need specialized analysis of any of the following issues.

Impact on Small Businesses and Other Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. chapter 6), agencies must prepare a proposed and final "regulatory flexibility analysis" (RFA) if the rulemaking could "have a significant impact on a substantial number of small entities." You should consider posting your RFA on the internet so the public can review your findings.

Your agency should have guidelines on how to prepare an RFA and you are encouraged to consult with the Chief Counsel for Advocacy of the Small Business Administration on expectations concerning what is an adequate RFA. Executive Order 13272 (67 FR 53461, August 16, 2002) requires you to notify the Chief Counsel for Advocacy of any draft rules that might have a significant economic impact on a substantial number of small entities. Executive Order 13272 also directs agencies to give every appropriate consideration to any comments provided by the Advocacy Office. Under SBREFA, EPA and OSHA are required to consult with small business prior to developing a proposed rule that would have a significant effect on small businesses. OMB encourages other agencies to do so as well.

Analysis of Unfunded Mandates

Under the Unfunded Mandates Act (2 U.S.C. 1532), you must prepare a written statement about benefits and costs prior to issuing a proposed or final rule (for which your agency published a proposed rule) that may result in aggregate expenditure by State, local, and tribal governments, or by the private sector, of \$100,000,000 or more in any one year (adjusted annually for inflation). Your analytical requirements under Executive Order 12866 are similar to the analytical requirements under this Act, and thus the same analysis may permit you to comply with both analytical requirements.

Information Collection, Paperwork, and Recordkeeping Burdens

Under the Paperwork Reduction Act (44 U.S.C. chapter 35), you will need to consider whether your rulemaking (or other actions) will create any additional information collection, paperwork or recordkeeping burdens. These burdens are permissible only if you can justify the practical utility of the information for the implementation of your rule. OMB approval will be required of any new requirements for a collection of information imposed on 10 or more persons and a valid OMB control number must be obtained for any covered paperwork. Your agency's CIO should be able to assist you in complying with the Paperwork Reduction Act.

Information Quality Guidelines

Under the Information Quality Law, agency guidelines, in conformance with the OMB government-wide guidelines (67 FR 8452, February 22, 2002), have established basic quality performance goals for all information disseminated by agencies, including information disseminated in support of proposed and final rules. The data and analysis that you use to support your rule must meet these agency and OMB quality standards. Your agency's CIO should be able to assist you in assessing information quality. The Statistical and Science Policy

Branch of OMB's Office of Information and Regulatory Affairs can provide you assistance. This circular defines OMB's minimum quality standards for regulatory analysis.

Environmental Impact Statements

The National Environmental Policy Act (42 U.S.C. 4321-4347) and related statutes and executive orders require agencies to consider the environmental impacts of agency decisions, including rulemakings. An environmental impact statement must be prepared for "major Federal actions significantly affecting the quality of the human environment." You must complete NEPA documentation before issuing a final rule. The White House Council on Environmental Quality has issued regulations (40 C.F.R. 1500-1508) and associated guidance for implementation of NEPA, available through CEQ's website (<http://www.whitehouse.gov/ceq/>).

Impacts on Children

Under Executive Order 13045, "Protection of Children from Environmental Health Risks and Safety Risks," each agency must, with respect to its rules, "to the extent permitted by law and appropriate, and consistent with the agency's mission," "address disproportionate risks to children that result from environmental health risks or safety risks." For any substantive rulemaking action that "is likely to result in" an economically significant rule that concerns "an environmental health risk or safety risk that an agency has reason to believe may disproportionately affect children," the agency must provide OMB/OIRA "an evaluation of the environmental health or safety effects of the planned regulation on children," as well as "an explanation of why the planned regulation is preferable to other potentially and reasonably feasible alternatives considered by the agency."

Energy Impacts

Under Executive Order 13211 (66 FR 28355, May 22, 2001), agencies are required to prepare and submit to OMB a Statement of Energy Effects for significant energy actions, to the extent permitted by law. This Statement is to include a detailed statement of "any adverse effects on energy supply, distribution, or use (including a shortfall in supply, price increases, and increased use of foreign supplies)" for the action and reasonable alternatives and their effects. You need to publish the Statement or a summary in the related NPRM and final rule. For further guidance, see OMB Memorandum 01-27 ("Guidance on Implementing Executive Order 13211", July 13, 2001), available on OMB's website.

G. Accounting Statement

You need to provide an accounting statement with tables reporting benefit and cost estimates for each major final rule for your agency. You should use the guidance outlined above to report these estimates. We have included a suggested format for your consideration.

Categories of Benefits and Costs

To the extent feasible, you should quantify all potential incremental benefits and costs. You should report benefit and cost estimates within the following three categories: monetized quantified, but not monetized; and qualitative, but not quantified or monetized.

These categories are mutually exclusive and exhaustive. Throughout the process of listing preliminary estimates of benefits and costs, agencies should avoid double-counting. This problem may arise if more than one way exists to express the same change in social welfare.

Quantifying and Monetizing Benefits and Costs

You should develop quantitative estimates and convert them to dollar amounts if possible. In many cases, quantified estimates are readily convertible, with a little effort, into dollar equivalents.

Qualitative Benefits and Costs

You should categorize or rank the qualitative effects in terms of their importance (e.g., certainty, likely magnitude, and reversibility). You should distinguish the effects that are likely to be significant enough to warrant serious consideration by decision makers from those that are likely to be minor.

Treatment of Benefits and Costs over Time

You should present undiscounted streams of benefit and cost estimates (monetized and net) for each year of the analytic time horizon. You should present annualized benefits and costs using real discount rates of 3 and 7 percent. The stream of annualized estimates should begin in the year in which the final rule will begin to have effects, even if the rule does not take effect immediately. Please report all monetized effects in 2001 dollars. You should convert dollars expressed in different years to 2001 dollars using the GDP deflator.

Treatment of Risk and Uncertainty

You should provide expected-value estimates as well as distributions about the estimates, where such information exists. When you provide only upper and lower bounds (in addition to best estimates), you should, if possible, use the 95 and 5 percent confidence bounds. Although we encourage you to develop estimates that capture the distribution of plausible outcomes for a particular alternative, detailed reporting of such distributions is not required, but should be available upon request.

The principles of full disclosure and transparency apply to the treatment of uncertainty. Where there is significant uncertainty and the resulting inferences and/or assumptions have a critical effect on the benefit and cost estimates, you should describe the benefits and costs under plausible alternative assumptions. You may add footnotes to the table as needed to provide documentation and references, or to express important warnings.

In a previous section, we identified some of the issues associated with developing estimates of the value of reductions in premature mortality risk. Based on this discussion, you should present alternative primary estimates where you use different estimates for valuing reductions in premature mortality risk.

Precision of Estimates

Reported estimates should reflect, to the extent feasible, the precision in the analysis. For example, an estimate of \$220 million implies rounding to the nearest \$10 million and thus a precision of +/- \$5 million; similarly, an estimate of \$222 million implies rounding to the nearest \$1 million and thus, a precision of +/- \$0.5 million.

Separate Reporting of Transfers

You should report transfers separately and avoid the misclassification of transfer payments as benefits or costs. Transfers occur when wealth or income is redistributed without any direct change in aggregate social welfare. To the extent that regulatory outputs reflect transfers rather than net welfare gains to society, you should identify them as transfers rather than benefits or costs. You should also distinguish transfers caused by Federal budget actions -- such as those stemming from a rule affecting Social Security payments -- from those that involve transfers between non-governmental parties -- such as monopoly rents a rule may confer on a private party. You should use as many categories as necessary to describe the major redistributive effects of a regulatory action. If transfers have significant efficiency effects in addition to distributional effects, you should report them.

Effects on State, Local, and Tribal Governments, Small Business, Wages and Economic Growth

You need to identify the portions of benefits, costs, and transfers received by State, local, and tribal governments. To the extent feasible, you also should identify the effects of the rule or program on small businesses, wages, and economic growth.³⁰ Note that rules with annual costs that are less than one billion dollars are likely to have a minimal effect on economic growth.

³⁰ The Regulatory Flexibility Act (5 U.S.C. 603(c), 604).

OMB #: Agency/Program Office:

Rule Title:

RIN#:

Date:

Category	Primary Estimate	Minimum Estimate	Maximum Estimate	Source Citation (RIA, preamble, etc.)
BENEFITS				
monetized benefits				
Annualized quantified, but unmonetized, benefits				
(unquantified) benefits				
COSTS				
Annualized monetized costs				
Annualized quantified, but unmonetized, costs				
Qualitative (unquantified) costs				
TRANSFERS				
Annualized monetized transfers: "on budget"				
from whom to whom?				
Annualized monetized transfers: "off-budget"				
From whom to whom?				
Category	<i>Effects</i>			Source Citation (RIA, preamble, etc.)
Effects on State, local, and/or tribal governments				
Effects on small businesses				
Effects on wages				
Effects on growth				

H. Effective Date

The effective date of this Circular is January 1, 2004 for regulatory analyses received by OMB in support of proposed rules, and January 1, 2005 for regulatory analyses received by OMB in support of final rules. In other words, this Circular applies to the regulatory analyses for draft proposed rules that are formally submitted to OIRA after December 31, 2003, and for draft final rules that are formally submitted to OIRA after December 31, 2004. (However, if the draft proposed rule is subject to the Circular, then the draft final rule will also be subject to the Circular, even if it is submitted prior to January 1, 2005.) To the extent practicable, agencies should comply earlier than these effective dates. Agencies may, on a case-by-case basis, seek a waiver from OMB if these effective dates are impractical.

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Monday, October 4, 1993

Presidential Documents

Title 3—

Executive Order 12866 of September 30, 1993

The President

Regulatory Planning and Review

The American people deserve a regulatory system that works for them, not against them: a regulatory system that protects and improves their health, safety, environment, and well-being and improves the performance of the economy without imposing unacceptable or unreasonable costs on society; regulatory policies that recognize that the private sector and private markets are the best engine for economic growth; regulatory approaches that respect the role of State, local, and tribal governments; and regulations that are effective, consistent, sensible, and understandable. We do not have such a regulatory system today.

With this Executive order, the Federal Government begins a program to reform and make more efficient the regulatory process. The objectives of this Executive order are to enhance planning and coordination with respect to both new and existing regulations; to reaffirm the primacy of Federal agencies in the regulatory decision-making process; to restore the integrity and legitimacy of regulatory review and oversight; and to make the process more accessible and open to the public. In pursuing these objectives, the regulatory process shall be conducted so as to meet applicable statutory requirements and with due regard to the discretion that has been entrusted to the Federal agencies.

Accordingly, by the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. *Statement of Regulatory Philosophy and Principles.*

(a) *The Regulatory Philosophy.* Federal agencies should promulgate only such regulations as are required by law, are necessary to interpret the law, or are made necessary by compelling public need, such as material failures of private markets to protect or improve the health and safety of the public, the environment, or the well-being of the American people. In deciding whether and how to regulate, agencies should assess all costs and benefits of available regulatory alternatives, including the alternative of not regulating. Costs and benefits shall be understood to include both quantifiable measures (to the fullest extent that these can be usefully estimated) and qualitative measures of costs and benefits that are difficult to quantify, but nevertheless essential to consider. Further, in choosing among alternative regulatory approaches, agencies should select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity), unless a statute requires another regulatory approach.

(b) *The Principles of Regulation.* To ensure that the agencies' regulatory programs are consistent with the philosophy set forth above, agencies should adhere to the following principles, to the extent permitted by law and where applicable:

- (1) Each agency shall identify the problem that it intends to address (including, where applicable, the failures of private markets or public institutions that warrant new agency action) as well as assess the significance of that problem.
- (2) Each agency shall examine whether existing regulations (or other law) have created, or contributed to, the problem that a new regulation is

intended to correct and whether those regulations (or other law) should be modified to achieve the intended goal of regulation more effectively.

(3) Each agency shall identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public.

(4) In setting regulatory priorities, each agency shall consider, to the extent reasonable, the degree and nature of the risks posed by various substances or activities within its jurisdiction.

(5) When an agency determines that a regulation is the best available method of achieving the regulatory objective, it shall design its regulations in the most cost-effective manner to achieve the regulatory objective. In doing so, each agency shall consider incentives for innovation, consistency, predictability, the costs of enforcement and compliance (to the government, regulated entities, and the public), flexibility, distributive impacts, and equity.

(6) Each agency shall assess both the costs and the benefits of the intended regulation and, recognizing that some costs and benefits are difficult to quantify, propose or adopt a regulation only upon a reasoned determination that the benefits of the intended regulation justify its costs.

(7) Each agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, and other information concerning the need for, and consequences of, the intended regulation.

(8) Each agency shall identify and assess alternative forms of regulation and shall, to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt.

(9) Wherever feasible, agencies shall seek views of appropriate State, local, and tribal officials before imposing regulatory requirements that might significantly or uniquely affect those governmental entities. Each agency shall assess the effects of Federal regulations on State, local, and tribal governments, including specifically the availability of resources to carry out those mandates, and seek to minimize those burdens that uniquely or significantly affect such governmental entities, consistent with achieving regulatory objectives. In addition, as appropriate, agencies shall seek to harmonize Federal regulatory actions with related State, local, and tribal regulatory and other governmental functions.

(10) Each agency shall avoid regulations that are inconsistent, incompatible, or duplicative with its other regulations or those of other Federal agencies.

(11) Each agency shall tailor its regulations to impose the least burden on society, including individuals, businesses of differing sizes, and other entities (including small communities and governmental entities), consistent with obtaining the regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations.

(12) Each agency shall draft its regulations to be simple and easy to understand, with the goal of minimizing the potential for uncertainty and litigation arising from such uncertainty.

Sec. 2. Organization. An efficient regulatory planning and review process is vital to ensure that the Federal Government's regulatory system best serves the American people.

(a) *The Agencies.* Because Federal agencies are the repositories of significant substantive expertise and experience, they are responsible for developing regulations and assuring that the regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order.

(b) *The Office of Management and Budget.* Coordinated review of agency rulemaking is necessary to ensure that regulations are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order, and that decisions made by one agency do not conflict with the policies or actions taken or planned by another agency. The Office of Management and Budget (OMB) shall carry out that review function. Within OMB, the Office of Information and Regulatory Affairs (OIRA) is the repository of expertise concerning regulatory issues, including methodologies and procedures that affect more than one agency, this Executive order, and the President's regulatory policies. To the extent permitted by law, OMB shall provide guidance to agencies and assist the President, the Vice President, and other regulatory policy advisors to the President in regulatory planning and shall be the entity that reviews individual regulations, as provided by this Executive order.

(c) *The Vice President.* The Vice President is the principal advisor to the President on, and shall coordinate the development and presentation of recommendations concerning, regulatory policy, planning, and review, as set forth in this Executive order. In fulfilling their responsibilities under this Executive order, the President and the Vice President shall be assisted by the regulatory policy advisors within the Executive Office of the President and by such agency officials and personnel as the President and the Vice President may, from time to time, consult.

Sec. 3. *Definitions.* For purposes of this Executive order: (a) "Advisors" refers to such regulatory policy advisors to the President as the President and Vice President may from time to time consult, including, among others: (1) the Director of OMB; (2) the Chair (or another member) of the Council of Economic Advisers; (3) the Assistant to the President for Economic Policy; (4) the Assistant to the President for Domestic Policy; (5) the Assistant to the President for National Security Affairs; (6) the Assistant to the President for Science and Technology; (7) the Assistant to the President for Intergovernmental Affairs; (8) the Assistant to the President and Staff Secretary; (9) the Assistant to the President and Chief of Staff to the Vice President; (10) the Assistant to the President and Counsel to the President; (11) the Deputy Assistant to the President and Director of the White House Office on Environmental Policy; and (12) the Administrator of OIRA, who also shall coordinate communications relating to this Executive order among the agencies, OMB, the other Advisors, and the Office of the Vice President.

(b) "Agency," unless otherwise indicated, means any authority of the United States that is an "agency" under 44 U.S.C. 3502(1), other than those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10).

(c) "Director" means the Director of OMB.

(d) "Regulation" or "rule" means an agency statement of general applicability and future effect, which the agency intends to have the force and effect of law, that is designed to implement, interpret, or prescribe law or policy or to describe the procedure or practice requirements of an agency. It does not, however, include:

- (1) Regulations or rules issued in accordance with the formal rulemaking provisions of 5 U.S.C. 556, 557;
- (2) Regulations or rules that pertain to a military or foreign affairs function of the United States, other than procurement regulations and regulations involving the import or export of non-defense articles and services;
- (3) Regulations or rules that are limited to agency organization, management, or personnel matters; or
- (4) Any other category of regulations exempted by the Administrator of OIRA.

(e) "Regulatory action" means any substantive action by an agency (normally published in the Federal Register) that promulgates or is expected to lead to the promulgation of a final rule or regulation, including notices

of inquiry, advance notices of proposed rulemaking, and notices of proposed rulemaking.

(f) "Significant regulatory action" means any regulatory action that is likely to result in a rule that may:

- (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities;
- (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or
- (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Sec. 4. *Planning Mechanism.* In order to have an effective regulatory program, to provide for coordination of regulations, to maximize consultation and the resolution of potential conflicts at an early stage, to involve the public and its State, local, and tribal officials in regulatory planning, and to ensure that new or revised regulations promote the President's priorities and the principles set forth in this Executive order, these procedures shall be followed, to the extent permitted by law:

(a) *Agencies' Policy Meeting.* Early in each year's planning cycle, the Vice President shall convene a meeting of the Advisors and the heads of agencies to seek a common understanding of priorities and to coordinate regulatory efforts to be accomplished in the upcoming year.

(b) *Unified Regulatory Agenda.* For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). Each agency shall prepare an agenda of all regulations under development or review, at a time and in a manner specified by the Administrator of OIRA. The description of each regulatory action shall contain, at a minimum, a regulation identifier number, a brief summary of the action, the legal authority for the action, any legal deadline for the action, and the name and telephone number of a knowledgeable agency official. Agencies may incorporate the information required under 5 U.S.C. 602 and 41 U.S.C. 402 into these agendas.

(c) *The Regulatory Plan.* For purposes of this subsection, the term "agency" or "agencies" shall also include those considered to be independent regulatory agencies, as defined in 44 U.S.C. 3502(10). (1) As part of the Unified Regulatory Agenda, beginning in 1994, each agency shall prepare a Regulatory Plan (Plan) of the most important significant regulatory actions that the agency reasonably expects to issue in proposed or final form in that fiscal year or thereafter. The Plan shall be approved personally by the agency head and shall contain at a minimum:

- (A) A statement of the agency's regulatory objectives and priorities and how they relate to the President's priorities;
- (B) A summary of each planned significant regulatory action including, to the extent possible, alternatives to be considered and preliminary estimates of the anticipated costs and benefits;
- (C) A summary of the legal basis for each such action, including whether any aspect of the action is required by statute or court order;
- (D) A statement of the need for each such action and, if applicable, how the action will reduce risks to public health, safety, or the environment, as well as how the magnitude of the risk addressed by the action relates to other risks within the jurisdiction of the agency;
- (E) The agency's schedule for action, including a statement of any applicable statutory or judicial deadlines; and

(F) The name, address, and telephone number of a person the public may contact for additional information about the planned regulatory action.

(2) Each agency shall forward its Plan to OIRA by June 1st of each year.

(3) Within 10 calendar days after OIRA has received an agency's Plan, OIRA shall circulate it to other affected agencies, the Advisors, and the Vice President.

(4) An agency head who believes that a planned regulatory action of another agency may conflict with its own policy or action taken or planned shall promptly notify, in writing, the Administrator of OIRA, who shall forward that communication to the issuing agency, the Advisors, and the Vice President.

(5) If the Administrator of OIRA believes that a planned regulatory action of an agency may be inconsistent with the President's priorities or the principles set forth in this Executive order or may be in conflict with any policy or action taken or planned by another agency, the Administrator of OIRA shall promptly notify, in writing, the affected agencies, the Advisors, and the Vice President.

(6) The Vice President, with the Advisors' assistance, may consult with the heads of agencies with respect to their Plans and, in appropriate instances, request further consideration or inter-agency coordination.

(7) The Plans developed by the issuing agency shall be published annually in the October publication of the Unified Regulatory Agenda. This publication shall be made available to the Congress; State, local, and tribal governments; and the public. Any views on any aspect of any agency Plan, including whether any planned regulatory action might conflict with any other planned or existing regulation, impose any unintended consequences on the public, or confer any unclaimed benefits on the public, should be directed to the issuing agency, with a copy to OIRA.

(d) *Regulatory Working Group.* Within 30 days of the date of this Executive order, the Administrator of OIRA shall convene a Regulatory Working Group ("Working Group"), which shall consist of representatives of the heads of each agency that the Administrator determines to have significant domestic regulatory responsibility, the Advisors, and the Vice President. The Administrator of OIRA shall chair the Working Group and shall periodically advise the Vice President on the activities of the Working Group. The Working Group shall serve as a forum to assist agencies in identifying and analyzing important regulatory issues (including, among others (1) the development of innovative regulatory techniques, (2) the methods, efficacy, and utility of comparative risk assessment in regulatory decision-making, and (3) the development of short forms and other streamlined regulatory approaches for small businesses and other entities). The Working Group shall meet at least quarterly and may meet as a whole or in subgroups of agencies with an interest in particular issues or subject areas. To inform its discussions, the Working Group may commission analytical studies and reports by OIRA, the Administrative Conference of the United States, or any other agency.

(e) *Conferences.* The Administrator of OIRA shall meet quarterly with representatives of State, local, and tribal governments to identify both existing and proposed regulations that may uniquely or significantly affect those governmental entities. The Administrator of OIRA shall also convene, from time to time, conferences with representatives of businesses, nongovernmental organizations, and the public to discuss regulatory issues of common concern.

Sec. 5. Existing Regulations. In order to reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments, and their industries; to determine whether regulations promulgated by the executive branch of the Federal Government have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not

duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive order, within applicable law; and to otherwise improve the effectiveness of existing regulations: (a) Within 90 days of the date of this Executive order, each agency shall submit to OIRA a program, consistent with its resources and regulatory priorities, under which the agency will periodically review its existing significant regulations to determine whether any such regulations should be modified or eliminated so as to make the agency's regulatory program more effective in achieving the regulatory objectives, less burdensome, or in greater alignment with the President's priorities and the principles set forth in this Executive order. Any significant regulations selected for review shall be included in the agency's annual Plan. The agency shall also identify any legislative mandates that require the agency to promulgate or continue to impose regulations that the agency believes are unnecessary or outdated by reason of changed circumstances.

(b) The Administrator of OIRA shall work with the Regulatory Working Group and other interested entities to pursue the objectives of this section. State, local, and tribal governments are specifically encouraged to assist in the identification of regulations that impose significant or unique burdens on those governmental entities and that appear to have outlived their justification or be otherwise inconsistent with the public interest.

(c) The Vice President, in consultation with the Advisors, may identify for review by the appropriate agency or agencies other existing regulations of an agency or groups of regulations of more than one agency that affect a particular group, industry, or sector of the economy, or may identify legislative mandates that may be appropriate for reconsideration by the Congress.

Sec. 6. *Centralized Review of Regulations.* The guidelines set forth below shall apply to all regulatory actions, for both new and existing regulations, by agencies other than those agencies specifically exempted by the Administrator of OIRA:

(a) *Agency Responsibilities.* (1) Each agency shall (consistent with its own rules, regulations, or procedures) provide the public with meaningful participation in the regulatory process. In particular, before issuing a notice of proposed rulemaking, each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected to be burdened by any regulation (including, specifically, State, local, and tribal officials). In addition, each agency should afford the public a meaningful opportunity to comment on any proposed regulation, which in most cases should include a comment period of not less than 60 days. Each agency also is directed to explore and, where appropriate, use consensual mechanisms for developing regulations, including negotiated rulemaking.

(2) Within 60 days of the date of this Executive order, each agency head shall designate a Regulatory Policy Officer who shall report to the agency head. The Regulatory Policy Officer shall be involved at each stage of the regulatory process to foster the development of effective, innovative, and least burdensome regulations and to further the principles set forth in this Executive order.

(3) In addition to adhering to its own rules and procedures and to the requirements of the Administrative Procedure Act, the Regulatory Flexibility Act, the Paperwork Reduction Act, and other applicable law, each agency shall develop its regulatory actions in a timely fashion and adhere to the following procedures with respect to a regulatory action:

(A) Each agency shall provide OIRA, at such times and in the manner specified by the Administrator of OIRA, with a list of its planned regulatory actions, indicating those which the agency believes are significant regulatory actions within the meaning of this Executive order. Absent a material change in the development of the planned regulatory action, those not designated as significant will not be subject to review under this section unless, within 10 working days of receipt

of the list, the Administrator of OIRA notifies the agency that OIRA has determined that a planned regulation is a significant regulatory action within the meaning of this Executive order. The Administrator of OIRA may waive review of any planned regulatory action designated by the agency as significant, in which case the agency need not further comply with subsection (a)(3)(B) or subsection (a)(3)(C) of this section.

(B) For each matter identified as, or determined by the Administrator of OIRA to be, a significant regulatory action, the issuing agency shall provide to OIRA:

- (i) The text of the draft regulatory action, together with a reasonably detailed description of the need for the regulatory action and an explanation of how the regulatory action will meet that need; and
- (ii) An assessment of the potential costs and benefits of the regulatory action, including an explanation of the manner in which the regulatory action is consistent with a statutory mandate and, to the extent permitted by law, promotes the President's priorities and avoids undue interference with State, local, and tribal governments in the exercise of their governmental functions.

(C) For those matters identified as, or determined by the Administrator of OIRA to be, a significant regulatory action within the scope of section 3(f)(1), the agency shall also provide to OIRA the following additional information developed as part of the agency's decision-making process (unless prohibited by law):

- (i) An assessment, including the underlying analysis, of benefits anticipated from the regulatory action (such as, but not limited to, the promotion of the efficient functioning of the economy and private markets, the enhancement of health and safety, the protection of the natural environment, and the elimination or reduction of discrimination or bias) together with, to the extent feasible, a quantification of those benefits;
- (ii) An assessment, including the underlying analysis, of costs anticipated from the regulatory action (such as, but not limited to, the direct cost both to the government in administering the regulation and to businesses and others in complying with the regulation, and any adverse effects on the efficient functioning of the economy, private markets (including productivity, employment, and competitiveness), health, safety, and the natural environment), together with, to the extent feasible, a quantification of those costs; and
- (iii) An assessment, including the underlying analysis, of costs and benefits of potentially effective and reasonably feasible alternatives to the planned regulation, identified by the agencies or the public (including improving the current regulation and reasonably viable nonregulatory actions), and an explanation why the planned regulatory action is preferable to the identified potential alternatives.

(D) In emergency situations or when an agency is obligated by law to act more quickly than normal review procedures allow, the agency shall notify OIRA as soon as possible and, to the extent practicable, comply with subsections (a)(3)(B) and (C) of this section. For those regulatory actions that are governed by a statutory or court-imposed deadline, the agency shall, to the extent practicable, schedule rule-making proceedings so as to permit sufficient time for OIRA to conduct its review, as set forth below in subsection (b)(2) through (4) of this section.

(E) After the regulatory action has been published in the Federal Register or otherwise issued to the public, the agency shall:

- (i) Make available to the public the information set forth in subsections (a)(3)(B) and (C);
- (ii) Identify for the public, in a complete, clear, and simple manner, the substantive changes between the draft submitted to OIRA for review and the action subsequently announced; and

(iii) Identify for the public those changes in the regulatory action that were made at the suggestion or recommendation of OIRA.

(F) All information provided to the public by the agency shall be in plain, understandable language.

(b) *OIRA Responsibilities.* The Administrator of OIRA shall provide meaningful guidance and oversight so that each agency's regulatory actions are consistent with applicable law, the President's priorities, and the principles set forth in this Executive order and do not conflict with the policies or actions of another agency. OIRA shall, to the extent permitted by law, adhere to the following guidelines:

(1) OIRA may review only actions identified by the agency or by OIRA as significant regulatory actions under subsection (a)(3)(A) of this section.

(2) OIRA shall waive review or notify the agency in writing of the results of its review within the following time periods:

(A) For any notices of inquiry, advance notices of proposed rulemaking, or other preliminary regulatory actions prior to a Notice of Proposed Rulemaking, within 10 working days after the date of submission of the draft action to OIRA;

(B) For all other regulatory actions, within 90 calendar days after the date of submission of the information set forth in subsections (a)(3)(B) and (C) of this section, unless OIRA has previously reviewed this information and, since that review, there has been no material change in the facts and circumstances upon which the regulatory action is based, in which case, OIRA shall complete its review within 45 days; and

(C) The review process may be extended (1) once by no more than 30 calendar days upon the written approval of the Director and (2) at the request of the agency head.

(3) For each regulatory action that the Administrator of OIRA returns to an agency for further consideration of some or all of its provisions, the Administrator of OIRA shall provide the issuing agency a written explanation for such return, setting forth the pertinent provision of this Executive order on which OIRA is relying. If the agency head disagrees with some or all of the bases for the return, the agency head shall so inform the Administrator of OIRA in writing.

(4) Except as otherwise provided by law or required by a Court, in order to ensure greater openness, accessibility, and accountability in the regulatory review process, OIRA shall be governed by the following disclosure requirements:

(A) Only the Administrator of OIRA (or a particular designee) shall receive oral communications initiated by persons not employed by the executive branch of the Federal Government regarding the substance of a regulatory action under OIRA review;

(B) All substantive communications between OIRA personnel and persons not employed by the executive branch of the Federal Government regarding a regulatory action under review shall be governed by the following guidelines: (i) A representative from the issuing agency shall be invited to any meeting between OIRA personnel and such person(s);

(ii) OIRA shall forward to the issuing agency, within 10 working days of receipt of the communication(s), all written communications, regardless of format, between OIRA personnel and any person who is not employed by the executive branch of the Federal Government, and the dates and names of individuals involved in all substantive oral communications (including meetings to which an agency representative was invited, but did not attend, and telephone conversations between OIRA personnel and any such persons); and

(iii) OIRA shall publicly disclose relevant information about such communication(s), as set forth below in subsection (b)(4)(C) of this section.

(C) OIRA shall maintain a publicly available log that shall contain, at a minimum, the following information pertinent to regulatory actions under review:

- (i) The status of all regulatory actions, including if (and if so, when and by whom) Vice Presidential and Presidential consideration was requested;
- (ii) A notation of all written communications forwarded to an issuing agency under subsection (b)(4)(B)(ii) of this section; and
- (iii) The dates and names of individuals involved in all substantive oral communications, including meetings and telephone conversations, between OIRA personnel and any person not employed by the executive branch of the Federal Government, and the subject matter discussed during such communications.

(D) After the regulatory action has been published in the Federal Register or otherwise issued to the public, or after the agency has announced its decision not to publish or issue the regulatory action, OIRA shall make available to the public all documents exchanged between OIRA and the agency during the review by OIRA under this section.

(5) All information provided to the public by OIRA shall be in plain, understandable language.

Sec. 7. Resolution of Conflicts. To the extent permitted by law, disagreements or conflicts between or among agency heads or between OMB and any agency that cannot be resolved by the Administrator of OIRA shall be resolved by the President, or by the Vice President acting at the request of the President, with the relevant agency head (and, as appropriate, other interested government officials). Vice Presidential and Presidential consideration of such disagreements may be initiated only by the Director, by the head of the issuing agency, or by the head of an agency that has a significant interest in the regulatory action at issue. Such review will not be undertaken at the request of other persons, entities, or their agents.

Resolution of such conflicts shall be informed by recommendations developed by the Vice President, after consultation with the Advisors (and other executive branch officials or personnel whose responsibilities to the President include the subject matter at issue). The development of these recommendations shall be concluded within 60 days after review has been requested.

During the Vice Presidential and Presidential review period, communications with any person not employed by the Federal Government relating to the substance of the regulatory action under review and directed to the Advisors or their staffs or to the staff of the Vice President shall be in writing and shall be forwarded by the recipient to the affected agency(ies) for inclusion in the public docket(s). When the communication is not in writing, such Advisors or staff members shall inform the outside party that the matter is under review and that any comments should be submitted in writing.

At the end of this review process, the President, or the Vice President acting at the request of the President, shall notify the affected agency and the Administrator of OIRA of the President's decision with respect to the matter.

Sec. 8. Publication. Except to the extent required by law, an agency shall not publish in the Federal Register or otherwise issue to the public any regulatory action that is subject to review under section 6 of this Executive order until (1) the Administrator of OIRA notifies the agency that OIRA has waived its review of the action or has completed its review without any requests for further consideration, or (2) the applicable time period in section 6(b)(2) expires without OIRA having notified the agency that it is returning the regulatory action for further consideration under section 6(b)(3), whichever occurs first. If the terms of the preceding sentence have not been satisfied and an agency wants to publish or otherwise issue a

regulatory action, the head of that agency may request Presidential consideration through the Vice President, as provided under section 7 of this order. Upon receipt of this request, the Vice President shall notify OIRA and the Advisors. The guidelines and time period set forth in section 7 shall apply to the publication of regulatory actions for which Presidential consideration has been sought.

Sec. 9. *Agency Authority.* Nothing in this order shall be construed as displacing the agencies' authority or responsibilities, as authorized by law.

Sec. 10. *Judicial Review.* Nothing in this Executive order shall affect any otherwise available judicial review of agency action. This Executive order is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

Sec. 11. *Revocations.* Executive Orders Nos. 12291 and 12498; all amendments to those Executive orders; all guidelines issued under those orders; and any exemptions from those orders heretofore granted for any category of rule are revoked.

A handwritten signature in black ink, reading "William Clinton". The signature is written in a cursive, flowing style.

THE WHITE HOUSE,
September 30, 1993.

[FR citation 58 FR 51735]